

EXHIBIT 17

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MINNESOTA

3 - - - - -

4 In Re:
5 Bair Hugger Forced Air Warming
6 Products Liability Litigation

7
8 This Document Relates To:

9 All Actions MDL No. 15-2666 (JNE/FLM)

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13 DEPOSITION OF ALBERT P. VAN DUREN

14 VOLUME I, PAGES 1 - 326

15 MARCH 7, 2017

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18 (The following is the deposition of ALBERT
19 P. VAN DUREN, taken pursuant to Notice of Taking
20 Deposition pursuant to Rule 30(b)(6) of the Federal
21 Rules of Civil Procedure, via videotape, at the
22 offices of Ciresi Conlin L.L.P., 225 South 6th Street,
23 Suite 4600, Minneapolis, Minnesota, commencing at
24 approximately 9:00 o'clock a.m., March 7, 2017.)

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I N D E X

EXHIBITS	DESCRIPTION	PAGE MARKED
Ex 350	Testing log, no Bates numbers	150
351	Warning label from the 200 Bair Hugger, no Bates numbers	310
WITNESS	EXAMINATION BY	PAGE
Albert P. Van Duren	Mr. Bankston	4
	Mr. Assaad	113
	Ms. Zimmerman	292

1 P R O C E E D I N G S

2 (Witness sworn.)

3 ALBERT P. VAN DUREN

4 called as a witness, being first duly sworn,
5 was examined and testified as follows:

09:00:40 6 ADVERSE EXAMINATION

09:00:40 7 BY MR. BANKSTON:

09:00:40 8 Q. Good morning, Mr. Van Duren.

09:00:42 9 A. Good morning.

09:00:42 10 Q. We're going to skip some of the formalities
09:00:45 11 because I know you've been in that chair before, done
09:00:47 12 some depositions, so we won't go over all of that
09:00:50 13 today; I'm sure you're up to speed. But before we
09:00:52 14 dive in, I did want to talk to you, make sure that you
09:00:55 15 understood exactly what kind of deposition it is we're
09:00:57 16 taking today, and -- and by that I mean that today you
09:01:00 17 are appearing as a corporate representative for 3M.
09:01:02 18 Do you feel like you have an understanding of what
09:01:04 19 that is and what your purpose is here today?

09:01:06 20 A. I believe so.

09:01:06 21 Q. Okay. I'm going to be asking you questions,
09:01:09 22 and in response to these questions today you're going
09:01:12 23 to be giving testimony as though you're the voice of
09:01:14 24 3M. Obviously, I can't put 3M in that chair, so
09:01:17 25 somebody has to be chosen. I've been informed that

09:01:20 1 you were the person that I need to talk to today about
09:01:22 2 some of the deposition topics that were in your
09:01:25 3 notice. How are you --

09:01:26 4 Have you reviewed those topics?

09:01:27 5 A. I have.

09:01:28 6 Q. Okay. Today I'm going to be talking to you
09:01:30 7 a little bit about the filter. The --

09:01:32 8 There are three filter topics which are in
09:01:34 9 that 30(b)(6) notice, and we're going to go over those
09:01:38 10 together and talk a little bit about those today. And
09:01:40 11 the first one I think we can knock out very quickly,
09:01:42 12 and it's because since the time of the notice I think
09:01:44 13 this issue has become more clear, but I want to talk
09:01:47 14 to you quickly about it, and that is the number two
09:01:50 15 topic was the identity of the filter manufacturer for
09:01:53 16 use in Bair Hugger units. And do you know who that is
09:01:55 17 here today?

09:01:56 18 A. Yes.

09:01:56 19 Q. Okay. And who does manufacture that filter?

09:01:58 20 A. It's -- it's made by Porous Media, which I
09:02:02 21 believe the company name has changed to Pentair.

09:02:05 22 Q. Okay. At any time during the run of --

09:02:09 23 Am I -- am I correct that any time during
09:02:11 24 the production run of the -- any Bair Hugger model,
09:02:13 25 the filter has always been made by that company and

09:02:15 1 not any other company?

09:02:16 2 MR. BLACKWELL: Let me interject an
09:02:18 3 objection to the form of the question; to be clear,
09:02:20 4 that Mr. Van Duren is the corporate representative on
09:02:22 5 the filter topics that were in the notice but only
09:02:25 6 with respect to the Bair Hugger 700 series and the 500
09:02:28 7 series products, so to the extent he's giving an
09:02:32 8 answer, the understanding is he's talking about those
09:02:34 9 models.

09:02:34 10 MR. BANKSTON: Okay.

09:02:35 11 Q. And with respect --

09:02:36 12 So my question is: For those two models --

09:02:39 13 And if you do have personal knowledge about
09:02:41 14 any other Bair Hugger units and possibly its filter,
09:02:44 15 please go ahead and let me know that you have that
09:02:45 16 personal knowledge.

09:02:46 17 But I'm asking you: At any time,
09:02:48 18 particularly with respect to those two models, do you
09:02:50 19 know if the filter manufacturer has ever changed?

09:02:52 20 A. To my knowledge, the manufacturer of the
09:02:55 21 filters for those two series has always been Porous
09:03:00 22 Media.

09:03:00 23 Q. Okay. Now I understand that 3M internally
09:03:03 24 makes filters. That's something it does.

09:03:05 25 A. Yes.

09:03:06 1 Q. Okay. Has any time 3M itself done anything
09:03:10 2 in-house related to the manufacture or fabrication of
09:03:13 3 that filter?

09:03:14 4 A. No, it has not.

09:03:15 5 Q. Okay. All right, Mr. Van Duren, I want to
09:03:20 6 talk to you a little bit about what you've done before
09:03:23 7 you came here today. And I assume there was some
09:03:26 8 preparation involved; is that correct?

09:03:26 9 A. Yes, --

09:03:28 10 Q. Okay.

09:03:28 11 A. -- there was some prep.

09:03:30 12 Q. For instance, many people who were involved
09:03:33 13 in the design and the selection and the testing of the
09:03:36 14 filter no longer work with the company. You
09:03:39 15 understand that?

09:03:40 16 A. Yes.

09:03:40 17 Q. Okay. Have any of those former employees
09:03:44 18 talked to you and told you about things you should be
09:03:47 19 saying in today's deposition?

09:03:49 20 MR. BLACKWELL: Object to the form of the
09:03:51 21 question, it goes beyond the scope of the Rule
09:03:54 22 30(b)(6) notice.

09:03:55 23 A. I haven't spoken to any of the people that
09:04:00 24 you've mentioned --

09:04:01 25 Q. Okay.

09:04:01 1 A. -- about -- about this topic.

09:04:03 2 Q. Okay. Then let's go ahead and expand that
09:04:05 3 beyond the topic we're talking about at hand, which is
09:04:08 4 to say all of your preparation for your 30(b)(6)
09:04:11 5 deposition. During that prepara -- preparation, did
09:04:13 6 you talk to any former employees?

09:04:15 7 A. Yes.

09:04:16 8 Q. Okay. Which former employees did you talk
09:04:18 9 to?

09:04:19 10 A. I've spoken to Brian Fisher.

09:04:21 11 Q. Okay. What did Mr. Fisher do for the
09:04:24 12 company?

09:04:24 13 A. He was a technician in the Research and
09:04:27 14 Development Department.

09:04:28 15 Q. Okay. When -- what --

09:04:30 16 Do you have an approximate date of his
09:04:32 17 employment?

09:04:32 18 A. From 1992 to 2017.

09:04:41 19 Q. Okay. And why --

09:04:44 20 Can you give me a summary of the subject
09:04:48 21 matter that you addressed with Mr. Fisher?

09:04:51 22 A. It was all part --

09:04:52 23 A personal nature. It had nothing to do
09:04:54 24 with this deposition.

09:04:55 25 Q. Ah, okay. Okay. I did want to make --

09:04:57 1 Well let me ask you on that question, just
09:05:00 2 limited to your preparation for the deposition itself,
09:05:02 3 have you talked to any former employees?

09:05:05 4 A. I have not.

09:05:06 5 Q. Okay. In preparing for your deposition,
09:05:12 6 have you reviewed anybody's testimony in this case?

09:05:14 7 A. Yes.

09:05:14 8 Q. Okay. Whose testimony have you reviewed?

09:05:17 9 A. I've reviewed Mike Reed's testimony, Paul
09:05:22 10 McGovern's testimony. I believe --

09:05:28 11 Q. If -- if you don't mind, let me just
09:05:29 12 interject for a second because I think maybe my
09:05:31 13 question wasn't totally artful, and that is, I'm
09:05:34 14 asking what deposition transcripts -- you know, I want
09:05:37 15 to make sure this is the question being answered -- I
09:05:40 16 want to know what deposition transcripts you read for
09:05:42 17 the purpose of preparing for this deposition, and
09:05:44 18 those names made me think that maybe that wasn't for
09:05:48 19 this specific deposition. But if I'm wrong, please
09:05:50 20 correct me.

09:05:50 21 MR. BLACKWELL: I believe that's what you
09:05:51 22 were answering; wasn't it, Mr. Van Duren?

09:05:54 23 THE WITNESS: That's what I was answering.

09:05:55 24 Q. Okay. So yes, so please forgive my
09:05:56 25 interruption. Can you let me know what deposition

09:05:58 1 transcripts you reviewed in preparation for this
09:06:00 2 deposition?

09:06:00 3 A. The -- the one --

09:06:01 4 The two that I mentioned, Mike -- Mike Reed
09:06:03 5 and Paul McGovern's testimony, and the -- the other
09:06:11 6 components that went with their testimony.

09:06:13 7 Q. Okay. Then would it be correct that you
09:06:18 8 have not reviewed any deposition testimony for any
09:06:20 9 current or former 3M employee?

09:06:24 10 MR. BLACKWELL: Object to the form of the
09:06:26 11 question as to timeframe.

09:06:30 12 A. Do you mean in preparation for this
09:06:31 13 testimony?

09:06:33 14 Q. Let's start broadly. Have you reviewed
09:06:35 15 that -- any deposition testimony at any time?

09:06:37 16 A. Yes, I've reviewed testimony.

09:06:39 17 Q. Okay. Was any of that testimony that you
09:06:42 18 reviewed done in preparation for this specific
09:06:45 19 deposition?

09:06:45 20 A. No.

09:06:45 21 Q. Okay.

09:06:46 22 A. Other than the two that I mentioned, Mike
09:06:48 23 Reed and Paul McGovern's testimony.

09:06:50 24 Q. Okay.

09:06:51 25 THE REPORTER: Let's go off the record a

09:06:53 1 moment, please.

09:07:51 2 (Discussion off the record.)

09:07:51 3 BY MR. BANKSTON:

09:07:53 4 Q. When you were preparing for this deposition,
09:07:55 5 did you feel the need to review any internal documents
09:07:58 6 from 3M?

09:08:01 7 A. I have reviewed some internal documents from
09:08:03 8 3M in -- in preparation for this testimony.

09:08:05 9 Q. Okay. And my question there also brings to
09:08:09 10 mind a clarification. I want to make sure that we're
09:08:11 11 both on the same page. Because sometimes I will say
09:08:14 12 "3M" and sometimes I may say generically "the
09:08:17 13 company." In the course of this deposition, you
09:08:18 14 understand 3M is the latest in the series of company
09:08:22 15 name changes as the maker of the Bair Hugger has gone
09:08:25 16 along; is that correct?

09:08:26 17 MR. BLACKWELL: I object to the foundation
09:08:27 18 for the question. If you want him to accept that for
09:08:29 19 purposes of your question, he will do it if you ask
09:08:32 20 him to.

09:08:32 21 Q. Sure. And all I'm asking is you understand
09:08:35 22 there was once an Augustine Medical, there was an
09:08:37 23 Arizant Healthcare, and then that was purchased by 3M.
09:08:39 24 You understand that generally; correct?

09:08:40 25 A. Yes.

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09:08:40 1 Q. For the purposes of this deposition I may
09:08:43 2 say "3M," for instance, "Has 3M doesn't X or Y,"
09:08:45 3 and -- and when I'm asking that I do mean throughout
09:08:48 4 the history of the company when the Bair Hugger was
09:08:50 5 made. So I'm going to do my best effort to use the
09:08:53 6 generic term "the company," but if I do slip and say
09:08:56 7 "3M," I want you to know for the purpose of this
09:09:00 8 deposition I want to mean the company as it has
09:09:01 9 existed through the make and model of the Bair Hugger
09:09:03 10 through all its history. Do you understand what I'm
09:09:06 11 saying by that?

09:09:07 12 A. I do understand.

09:09:07 13 Q. Okay. Now when you reviewed documents for
09:09:10 14 this deposition, what kind of documents were you
09:09:13 15 looking for?

09:09:15 16 A. I -- I reviewed, as I mentioned, the
09:09:21 17 testimony of the two individuals I previously
09:09:23 18 mentioned. I've also reviewed internal e-mails, ECOs,
09:09:35 19 instructions for use, product manuals, those -- those
09:09:41 20 sorts of things.

09:09:42 21 Q. Okay. ECO, can you define that for me?

09:09:45 22 A. That's an engineering change order.

09:09:47 23 Q. Okay.

09:09:47 24 A. That -- that's a method companies use to
09:09:50 25 document any sort of change that occurs in the

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09:09:54 1 production of a device, to keep track of any sort of
09:09:59 2 specific change that's made in the construction or
09:10:02 3 manufacture of the device.

09:10:03 4 Q. Okay. What kind of design changes were you
09:10:05 5 looking at?

09:10:06 6 A. I looked at some ECOs that had to do with
09:10:11 7 filter changes and specifications.

09:10:15 8 Q. Okay. Were you given any kind of outline to
09:10:23 9 review?

09:10:30 10 A. No, I don't believe I was given an outline.
09:10:33 11 I did review the document that I believe your law firm
09:10:38 12 sent regarding the -- several --

09:10:42 13 MR. BLACKWELL: The notice itself?

09:10:43 14 A. -- statements --

09:10:43 15 MR. BLACKWELL: Oh, go ahead. I'm sorry.

09:10:45 16 A. No, no, that's all right.

09:10:47 17 The statements that -- that I was either
09:10:49 18 supposed to agree with or disagree with.

09:10:52 19 Q. Okay.

09:10:52 20 A. I think that was the closest to an outline
09:10:55 21 that I had.

09:10:55 22 Q. Okay. We can jump right into first topic
09:10:58 23 that I'm going to be talking with you today, which is
09:11:00 24 the filtration efficiency of the Bair Hugger 700
09:11:04 25 series and 500 series products that were allegedly

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09:11:07 1 used in the plaintiffs' surgeries at issue in this
09:11:10 2 litigation. You understand what you've --

09:11:12 3 In other words, you have taken some efforts
09:11:13 4 to prepare yourself to talk about those topics?

09:11:15 5 A. I have.

09:11:16 6 Q. Okay. "Filter efficiency," what does that
09:11:21 7 mean?

09:11:24 8 A. Has to do with the percentage of particles
09:11:29 9 captured by a filter of a given size relative to the
09:11:34 10 number of particles that pass through the filter.

09:11:36 11 Q. Okay. Now in this topic we're talking about
09:11:41 12 two Bair Hugger products, the 500 series and the 700
09:11:44 13 series, and so we're going to divide them out, and I
09:11:47 14 want to talk about the 500 series first.

09:11:48 15 You understand that when the 500 series was
09:11:51 16 released it was marketed with a high-efficiency .2-
09:11:54 17 micron filter.

09:11:56 18 A. Yes.

09:11:57 19 Q. Okay. Has the 500 series always had the
09:12:00 20 same filter?

09:12:04 21 A. I believe that the 500 series -- well the --

09:12:08 22 So when we say "500 series," that includes
09:12:11 23 a -- a large number of individual models, so there was
09:12:14 24 a -- an initial 500 and a 500 OR and then a 502 and
09:12:21 25 then a 505. My understanding is that the filters in

09:12:25 1 those units were not always the same filter media.

09:12:29 2 Q. Okay. And when you say "the filters in

09:12:33 3 those units were not always the same," are you

09:12:35 4 distinguishing between units, as in, say, the 500 has

09:12:38 5 a different filter than the 505, or did all units have

09:12:42 6 the same filter during whatever time period they had a

09:12:44 7 filter?

09:12:45 8 A. They -- they had different physical sizes,

09:12:50 9 right. Some --

09:12:51 10 The 505, for example, was a cylindrical

09:12:54 11 filter, the others are more rectangular, pleated

09:12:59 12 filters. And I -- I believe that the filter media

09:13:04 13 throughout the 500 was the same material, though,

09:13:07 14 throughout the 500 series.

09:13:09 15 Q. Okay. So let's --

09:13:11 16 I want to talk specifically about the model

09:13:12 17 505.

09:13:13 18 A. Okay.

09:13:13 19 Q. In other words, your testimony is that when

09:13:17 20 the 505 was released with the filter that it had, it

09:13:21 21 has had that same filter media throughout the design

09:13:25 22 of the unit.

09:13:26 23 A. I believe that the -- in the 505 unit, that

09:13:31 24 the filter media at some point did change. The

09:13:35 25 physical size of the filter remained the same but the

09:13:37 1 filter media did change.

09:13:40 2 Q. Okay. And so I guess a corollary to that
09:13:44 3 would be: Does the 505, throughout the life of the
09:13:47 4 unit, has it always had the same filter efficiency?

09:13:52 5 A. No.

09:13:54 6 Q. Okay. So essentially there's --
09:13:58 7 And I'm assuming that has changed once, or
09:13:59 8 has it changed multiple times?

09:14:01 9 A. To my knowledge, it's changed once.

09:14:03 10 Q. Okay. So ultimately there are two styles of
09:14:06 11 filter that we can talk about with regard to the model
09:14:09 12 505.

09:14:10 13 A. That's correct.

09:14:10 14 Q. Okay. Now the model 505 was FDA cleared in
09:14:16 15 1996. Does that sound right to you?

09:14:19 16 A. The --

09:14:21 17 Yeah, I think it's around that timeframe. I
09:14:23 18 joined the company in 1994. We were -- it was just
09:14:27 19 coming out at that point, so somewhere in that
09:14:29 20 timeframe seems about right.

09:14:30 21 Q. Okay. Are you familiar with the claims made
09:14:34 22 about the filter in federal clearance?

09:14:38 23 A. Generally speaking, yes.

09:14:40 24 Q. Okay. So you'll -- you'll agree with me
09:14:43 25 that in the 505 federal clearance there is discussion

09:14:47 1 of its filter.

09:14:48 2 A. You mean in the FDA 510(k) premarket

09:14:53 3 notif --

09:14:54 4 Q. Yes, sir.

09:14:54 5 A. -- notification?

09:14:55 6 There is some discussion about the filter.

09:14:56 7 Q. Okay. Now that filter, which was cleared in
09:14:59 8 1996, when did that filter design or medium, when did
09:15:03 9 that change?

09:15:05 10 A. I -- I'm not certain what year that that --
09:15:11 11 that occurred. I don't know.

09:15:13 12 Q. That's something that the corporation
09:15:15 13 certainly could know; correct?

09:15:16 14 A. There would be an ECO specifying that
09:15:21 15 change, yes.

09:15:21 16 Q. Okay. And you have reviewed ECOs in this
09:15:24 17 case.

09:15:24 18 A. I have.

09:15:24 19 Q. Okay.

09:15:25 20 A. But I do not recall the year that that
09:15:27 21 changed.

09:15:27 22 Q. Okay. Do you have any general ballpark
09:15:29 23 about at what period during this -- the history of the
09:15:32 24 product, if not a specific year?

09:15:35 25 A. I believe in the 2000s somewhere it changed.

09:15:37 1 Q. Okay. Do you have any understanding of
09:15:41 2 what -- of the impetus behind that change?

09:15:44 3 A. I believe that the company, Porous Media, at
09:15:47 4 the time was unable to produce the same filter media
09:15:52 5 that we had used in the previous versions of the 505.

09:15:59 6 Q. That first filter that was used in the model
09:16:10 7 505, do you know its model name or designation, a way
09:16:13 8 to identify it?

09:16:14 9 A. I -- I don't know its model or part number,
09:16:16 10 no.

09:16:17 11 Q. Okay. Have you encountered any documents in
09:16:20 12 your review that discuss the M10 filter?

09:16:23 13 A. Well M10 is a media, it's not really the
09:16:27 14 filter itself.

09:16:28 15 Q. Okay.

09:16:29 16 A. It's the media that is placed into the
09:16:32 17 filter.

09:16:32 18 Q. Okay.

09:16:34 19 A. I'm generally familiar with that term, yes.

09:16:36 20 Q. Okay. So let's talk a little bit about the
09:16:38 21 filter media then. The designation for the first
09:16:41 22 filter, then, would be the M10 media. You'll agree
09:16:44 23 with that?

09:16:45 24 A. I believe so. That is correct.

09:16:46 25 Q. Do you -- do you know the designation for

09:16:49 1 the -- the replacement media?

09:16:51 2 A. I believe it's M20.

09:16:52 3 Q. Okay. Now since we're talking about filter
09:16:56 4 efficiency, do you know, sitting here today, how you
09:16:58 5 would describe the filter efficiency of the M10 media?

09:17:02 6 A. I believe it meets the MERV 14 standard.

09:17:06 7 Q. Okay. That filter was marketed to the
09:17:10 8 public as a .2-micron filter; correct?

09:17:12 9 A. It was -- it was designated --

09:17:17 10 I guess that's its -- its nomenclature. I
09:17:21 11 don't think we marketed the filter per se, but it was
09:17:23 12 specified -- or its nomenclature had 0.2 micron as a
09:17:30 13 designation.

09:17:30 14 Q. And you do understand that that term has
09:17:32 15 been in public communications; correct?

09:17:34 16 A. Yes.

09:17:34 17 Q. Okay. Can you tell me what the filter
09:17:37 18 efficiency was at .2 microns for the M10 media?

09:17:42 19 A. I -- I don't know what its efficiency was at
09:17:46 20 that particulate size.

09:17:47 21 Q. Okay. What about the second filter, the M20
09:17:52 22 media, can you tell me how efficient that filter is at
09:17:55 23 .2 microns?

09:17:56 24 A. I don't know exactly what its efficiency is
09:17:59 25 at .2 microns.

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09:18:00 1 Q. That's something that's available to the
09:18:02 2 company if it wanted to know.

09:18:03 3 A. Oh, certainly.

09:18:04 4 Q. Right. And it was something that's
09:18:06 5 reasonably available in their files.

09:18:08 6 A. Of course.

09:18:09 7 Q. That's something you don't know today.

09:18:10 8 A. I don't know specifically what it is.

09:18:11 9 Q. Okay. So your preparation to talk to me
09:18:15 10 today about the filtration efficiency of your .2-
09:18:19 11 micron filters, in doing so you did not come prepared
09:18:22 12 today to tell me what the filter efficiency was at .2
09:18:25 13 microns.

09:18:26 14 MR. BLACKWELL: Well let me object to the --
09:18:28 15 the -- the question. The -- the -- the topic in the
09:18:30 16 30(b) -- 30(b)(6) notice was the filtration efficiency
09:18:33 17 of the Bair Hugger 700 series and 500 series and not
09:18:37 18 specifically the filter efficiency of the Bair Hugger
09:18:40 19 500 series at 0.2 microns, and so I think it misstated
09:18:46 20 the -- the topic. But with that said --

09:18:47 21 MR. BANKSTON: I'm not -- I'm not stating
09:18:49 22 the topic to you, sir. What I want to -- what I --

09:18:51 23 MR. BLACKWELL: What I said, you can -- you
09:18:52 24 can answer his question if -- if you're able to answer
09:18:53 25 it.

09:18:54 1 Q. Can you -- do you know if you --

09:18:56 2 Can you tell me right now that you did not

09:18:58 3 prepare to talk about the filtration efficiency of the

09:19:02 4 .2-micron filter at .2 microns?

09:19:06 5 A. Well I -- I don't recall. I -- I believe

09:19:08 6 it's around 63, 64 percent, something like that, but I

09:19:13 7 don't recall specifically what its filtration

09:19:15 8 efficiency is at 0.2 microns.

09:19:18 9 Q. Okay.

09:19:19 10 MR. BLACKWELL: You're not required to guess

09:19:20 11 or speculate. Remember that.

09:19:23 12 Q. Yes. And to -- and to follow back on that,

09:19:26 13 when you I believe gave me what you thought was an

09:19:29 14 estimate or some measure of recollection, that's not

09:19:31 15 as a result of any specific preparation for this

09:19:34 16 deposition.

09:19:34 17 MR. BLACKWELL: Object to the form of the

09:19:36 18 question.

09:19:37 19 A. Well there were many topics that we prepared

09:19:41 20 for for this deposition. I'm recalling what I think

09:19:44 21 is the correct number.

09:19:46 22 Q. Okay. You --

09:19:49 23 Did you review filtration efficiency testing

09:19:52 24 prior to this deposition?

09:19:52 25 A. I did not review efficiency testing.

22

09:19:57 1 Q. Okay. You -- you understand that is also
09:20:01 2 available to the company.

09:20:02 3 A. Yes.

09:20:02 4 Q. Okay. Now you had made a statement about
09:20:15 5 the first M10 media, that you believe it fell into
09:20:19 6 what was known as the MERV 14 category; correct?

09:20:21 7 A. Correct.

09:20:22 8 Q. Okay. The M20 filter media, do you have an
09:20:27 9 understanding of what its MERV rating would be?

09:20:29 10 A. Also MERV 14.

09:20:31 11 Q. Okay. However, you will agree with me that
09:20:34 12 those two filters do have different efficiencies.

09:20:37 13 A. The -- the filter media, they have different
09:20:41 14 efficiencies, correct.

09:20:42 15 Q. Okay. Now in other words, the --
09:20:44 16 You're stating that the difference in filter
09:20:47 17 media between the two units, both of those fall within
09:20:51 18 the range of MERV 14.

09:20:53 19 A. That is correct.

09:20:54 20 Q. Okay. Do you know sitting here today what
09:21:01 21 the company relied on to reach the conclusion that
09:21:03 22 each of these filters was MERV 14?

09:21:07 23 A. There was --

09:21:08 24 Some independent testing was conducted to
09:21:11 25 confirm that.

09:21:12 1 Q. Okay. Have you reviewed that testing?

09:21:14 2 A. No, I have not reviewed that testing.

09:21:17 3 Q. Okay. I want to talk to you a little bit

09:21:23 4 now about the -- your --

09:21:30 5 Oh, excuse me. I pulled my mic too hard.

09:21:33 6 I want to talk to you now about filtration

09:21:35 7 efficiency and how it relates to the design choices

09:21:38 8 with the Bair Hugger, and so first starting with the

09:21:40 9 model 500 series, and I want to focus -- let's --

09:21:44 10 First let's talk about the model 500 series

09:21:46 11 for a minute just so we can -- I understand it's not

09:21:50 12 a topic, I don't expect you to be fully prepared on

09:21:52 13 it, but I want to make sure we're talking in the same

14 language.

09:21:54 15 When you said that there are several

09:21:55 16 different units, am I right that that's the 500, the

09:21:58 17 500 OR and the 505?

09:21:59 18 A. And the 502.

09:22:01 19 Q. Oh, there's a 502 as well. Okay.

09:22:04 20 Can you briefly summarize the differences

09:22:07 21 between those units for me?

09:22:09 22 MR. BLACKWELL: Object to the form of the

09:22:09 23 question as beyond the scope of the 30(b)(6), and the

09:22:13 24 answers do not bind 3M.

09:22:15 25 MR. BANKSTON: You can answer.

24

09:22:16 1 A. So beginning with the 500 series, these were
09:22:21 2 smaller warming units that were mounted on wheels and
09:22:28 3 were -- could be moved from room to room. They had
09:22:31 4 a -- a rectangular filter in -- in them, and they were
09:22:36 5 also designed for use in the operating room, so the
09:22:40 6 nozzle temperatures were reduced to approximately 43
09:22:44 7 Celsius, and so all of that series of warming units,
09:22:49 8 including the ones for the European market, had lower
09:22:55 9 nozzle temperatures, which made them suitable for use
09:22:57 10 in the operating room.

09:22:58 11 Q. Okay. Between the -- any of the models of
09:23:07 12 the 500 series, would you characterize them as any of
09:23:10 13 them having significant differences in the way their
09:23:14 14 filter performed and how efficient it was when those
09:23:17 15 units were released?

09:23:20 16 A. I do not believe there were significant
09:23:22 17 differences in the way the filters performed --

09:23:24 18 Q. Okay.

09:23:25 19 A. -- in the whole series.

09:23:28 20 Q. The 500 and then the 500 OR, does that "OR"
09:23:33 21 designation stand for Operating Room?

09:23:34 22 A. Yes.

09:23:35 23 Q. Okay. And in what way -- is -- is this
09:23:39 24 what --

09:23:39 25 The discussion you were having there as the

09:23:41 1 difference between the 500 and the OR, is the changes
09:23:43 2 you talked about making it suitable for operating room
09:23:46 3 use?

09:23:46 4 A. That was -- that was one among many changes
09:23:50 5 that were made in that series of warming units to
09:23:54 6 distinguish them from warming units that were
09:23:58 7 specifically designed for use in the PACU or the ICU.

09:24:02 8 Q. Okay. What is the purpose of having a
09:24:07 9 filter on the Bair Hugger?

09:24:11 10 A. Well it had several purposes: one purpose
09:24:13 11 is to prevent the fouling of the internal components
09:24:17 12 of the Bair Hugger; the other is to reduce the
09:24:21 13 particulates that enter and exit the Bair Hugger.

09:24:24 14 Q. As -- in the field of --

09:24:31 15 When designing the Bair Hugger, why did the
09:24:32 16 company care about particulates coming in and out of
09:24:35 17 the Bair Hugger?

09:24:37 18 A. To keep the electronics and the sensors, the
09:24:41 19 fans and the heat exchangers from gathering debris and
09:24:45 20 fouling.

09:24:46 21 Q. Okay. When -- when -- I'm --

09:24:49 22 What I'm specifically referring to is that
09:24:52 23 when I asked you for the purpose, you gave me two
09:24:54 24 purposes, one being to foul -- not to foul up the
09:24:58 25 motor and the other to reduce particulates in and out

09:25:01 1 of the Bair Hugger. Are those two sides of the same
09:25:03 2 coin or are those two different things?

09:25:05 3 A. They're -- they're two different things.

09:25:06 4 Q. Okay. So in other words, I understand that
09:25:08 5 one of the purposes was to prevent the fouling of the
09:25:10 6 motor, things going into the Bair Hugger.

09:25:12 7 A. Well it's -- it's not just the motor. I
09:25:15 8 mean the -- all of the sensing and heat-exchanger
09:25:19 9 components of the entire warming unit work better when
09:25:25 10 they're not fouled.

09:25:26 11 Q. Okay. So kind of a shorthand for that is
09:25:31 12 the safety and welfare of the internal components, the
09:25:34 13 actual machinery that's being considered with the
09:25:37 14 filter, that's what its -- one of its purposes to be
09:25:40 15 there.

09:25:40 16 A. Well I wouldn't say the safety. We -- we
09:25:44 17 want the unit to operate within certain limits of
09:25:50 18 specifications, and in order to ensure that those
09:25:54 19 operating limits are met, the unit -- the components
09:25:58 20 in the unit have to remain unfouled.

09:26:00 21 Q. Okay. All right. So we have that purpose
09:26:02 22 for the filter. And I understand that the filter
09:26:05 23 plays a role in keeping the device operational. You
09:26:08 24 will agree with that?

09:26:09 25 A. Yes.

09:26:09 1 Q. Okay. But in terms of particulates coming
09:26:12 2 in and out of the Bair Hugger, was the company's only
09:26:15 3 concern the -- the continued operation of the unit?

09:26:19 4 A. No. There -- there was also concern of
09:26:22 5 keeping particulates out of the exhaust flow from the
09:26:27 6 warming unit --

09:26:28 7 Q. Okay.

09:26:28 8 A. -- into the blanket.

09:26:29 9 Q. Why -- okay. Why did the company care about
09:26:32 10 keeping particulates out of the exhaust flow of the
09:26:35 11 warming unit?

09:26:36 12 A. Well it just made -- it made sense not to
09:26:41 13 put particulates into the -- into the blanket.

09:26:45 14 Q. I don't want to be like my six-year-old is
09:26:48 15 on these sorts of questions, but why don't you want to
09:26:50 16 put particulates into the blanket?

09:26:51 17 A. Well there was no reason to blow
09:26:54 18 particulates into the -- into the blanket, which might
09:26:56 19 end up leaving the blanket.

09:26:58 20 Q. Okay. Why does the company care if
09:27:00 21 particulates leave the blanket?

09:27:01 22 A. Well there's always the -- there's --
09:27:05 23 there's always the potential for increasing the level
09:27:08 24 of pollution in the operating room, so this is one
09:27:11 25 method of reducing that possibility.

09:27:13 1 Q. Okay. When we talk about pollution in the
09:27:16 2 operating room, what does that mean to you?

09:27:19 3 A. Well, the particulate load in -- within the
09:27:22 4 operating room.

09:27:23 5 Q. Okay. When making filter decisions, making
09:27:30 6 these design decisions and understanding that there is
09:27:32 7 an issue that -- as you call it, pollution in the
09:27:34 8 operating room, again I hate to go down this -- keep
09:27:41 9 doing this, but why is pollution, things coming out of
09:27:44 10 the Bair Hugger in the OR, why was that a concern for
09:27:46 11 the company?

09:27:47 12 A. Well again, we -- there was --

09:27:51 13 There's no reason to increase the
09:27:54 14 particulate load that's being blown into the blanket
09:27:57 15 which is on a patient.

09:27:59 16 Q. Okay. So I understand there's no reason to
09:28:02 17 put particulates onto a patient. Is there any reason
09:28:06 18 not to?

09:28:09 19 MR. BLACKWELL: Yeah. I object to the form
09:28:10 20 of the question. If you understand it, you can answer
09:28:13 21 it.

09:28:13 22 A. I'm not -- I'm not sure I --

09:28:15 23 Q. Let me try to rephrase that right.

09:28:17 24 A. Okay.

09:28:17 25 Q. Because from what I understand from your

09:28:19 1 answer, it is there's an event that could happen,
09:28:21 2 particulates could be blown through the blanket, end
09:28:24 3 up near the patient. Okay? That's our first
09:28:26 4 proposition.

09:28:27 5 A. I -- I believe --

09:28:27 6 MR. BLACKWELL: I object to counsel's
09:28:30 7 characterization and move to strike it. His testimony
09:28:31 8 stands for what it was.

09:28:31 9 MR. BANKSTON: What are we doing, Jerry?
09:28:32 10 Seriously man, why are you doing that?

09:28:32 11 MR. BLACKWELL: I'm objecting for the
09:28:34 12 record. So you can go ahead with your question. I
09:28:35 13 object for the record.

09:28:36 14 MR. OGDEN: You're a -- you're a --

09:28:36 15 MR. BLACKWELL: Really, really. I objected
09:28:39 16 for the record. That's really what I'm doing.

09:28:39 17 MR. OGDEN: Now you're a really experienced
09:28:40 18 lawyer. You know not to do that. Right?

09:28:42 19 MR. BLACKWELL: Well, and you're an
09:28:43 20 experienced lawyer, so you know I object for the
09:28:44 21 record.

09:28:44 22 MR. OGDEN: I'm really not the --

09:28:44 23 No. I'm the kid. I'm learning here today.

09:28:46 24 MR. BLACKWELL: Well I must be, too. But
09:28:49 25 I'm objecting for the record.

09:28:50 1 MR. OGDEN: That's one way of doing it.

09:28:53 2 Q. All right. Let's talk again about -- try to
09:28:54 3 walk through this. Right?

09:28:56 4 From what I first understood is that there
09:28:56 5 was a condition that could be -- exist that the filter
09:28:58 6 was meant to address, which is the delivery of
09:29:00 7 particulates through the blanket and onto the patient.
09:29:03 8 Do you understand that?

09:29:04 9 A. Yes.

09:29:04 10 Q. Okay. What I understood your answer to be
09:29:07 11 is that there is no reason to do that, there is no
09:29:10 12 reason to blow particulates onto the patient; right?

09:29:15 13 A. That's correct.

09:29:15 14 Q. Okay. From that answer, are --

09:29:18 15 When you say there's no reason, does that
09:29:21 16 mean there's no benefit or purpose to blowing
09:29:23 17 particulates onto the patient? You understand what I
09:29:26 18 mean?

09:29:26 19 A. There's -- there is no benefit for doing
09:29:29 20 that, correct.

09:29:30 21 Q. Right. There we have that there's no reason
09:29:33 22 not to do it, right -- there's no -- there's no reason
09:29:35 23 to do it. You see what I'm saying? I'm wondering:
09:29:38 24 Is there a reason not to do it?

09:29:40 25 MR. BLACKWELL: Object to the form of the

09:29:41 1 question.

09:29:42 2 A. Well there is -- it --

09:29:44 3 It's just an appeal to reason. You don't

09:29:46 4 want to increase unnecessarily the -- any particulates

09:29:50 5 that are entering the blanket.

09:29:53 6 Q. Again, because that would --

09:29:54 7 Is that for the same reason of pollution in

09:29:56 8 the OR?

09:29:57 9 A. Yes.

09:29:57 10 Q. Okay. And so again with respect to

09:30:01 11 pollution in the OR, what is it that the company is

09:30:05 12 concerned will happen if there's pollution in the OR?

09:30:10 13 A. Well a lot of effort is expended in a modern

09:30:14 14 operating room to reduce the particulate load in and

09:30:19 15 around the surgical site of the patient, and this is

09:30:21 16 just one of the many practices that are employed to do

09:30:26 17 that.

09:30:27 18 Q. What is that practice meant to do?

09:30:30 19 A. Well it --

09:30:32 20 Again, the -- the thinking is that reducing

09:30:34 21 the number of particulates in the air in the operating

09:30:38 22 room has some effect on reducing the risk of

09:30:43 23 developing a surgical-site infection.

09:30:44 24 Q. All right. With respect to the model 505 --

09:30:58 25 And actually, first, just to make sure we're

09:31:00 1 on the same topic, I want to read to you the topic
09:31:02 2 that we're going to be discussing right now, and this
09:31:04 3 was the third topic in your deposition notice, and
09:31:07 4 this topic was decisions relating to filter design,
09:31:11 5 filter mediums, and filter efficiency of the Bair
09:31:15 6 Hugger 700 series and 500 series products allegedly
09:31:19 7 used in plaintiffs' surgeries at issue in this
09:31:20 8 litigation, including safety validation for filter
09:31:24 9 design decisions.

09:31:25 10 Now we've already started talking a little
09:31:27 11 bit about that, but in terms of those filter design
09:31:30 12 decisions, let's talk about with respect to the model
09:31:33 13 505, who was responsible for making the decision about
09:31:36 14 what filter to use and what filter medium to use on
09:31:39 15 the 505 series?

09:31:40 16 A. Well I suspect --

09:31:44 17 Well the decisions were a combined group of
09:31:50 18 people, that would include marketing, research and
09:31:53 19 development, sales, people working to develop design
09:32:00 20 specifications so that the product would meet customer
09:32:05 21 requirements, --

09:32:06 22 Q. Okay.

09:32:06 23 A. -- so there were a -- a number of people
09:32:08 24 involved in making those decisions.

09:32:10 25 Q. Okay. So pretend for the moment, say if the

33

09:32:20 1 CEO wants to talk and find out who do I talk to to
09:32:25 2 discuss the decision that was made for what level of
09:32:28 3 filtration was used on the model 505, is -- is your
09:32:32 4 response that I'd pretty much have to talk to
09:32:35 5 everybody, or is there somebody in particular that
09:32:39 6 could be spoken to who can be connected with the
09:32:40 7 filter design decisions?

09:32:41 8 A. Well I think that in that -- in -- in that
09:32:44 9 context, a design requirements specification document
09:32:49 10 would lay out the reasons for the decision to
09:32:54 11 incorporate a certain kind of filter, and then the
09:32:57 12 people involved in that decision's names are recorded
09:33:02 13 on those design requirements specifications just like
09:33:04 14 they are on every other design document like ECOs and
09:33:08 15 post-market surveillance and that sort of thing. So
09:33:10 16 again, yes, a group of -- a number of people would
09:33:14 17 have been involved in hashing out those kinds of
09:33:18 18 design requirements.

09:33:18 19 Q. Okay. How was the decision made to arrive
09:33:25 20 at the level of filtration efficiency used in the
09:33:29 21 model 505?

09:33:33 22 A. I do not know personally. I don't --
09:33:35 23 The company doesn't know how that number was
09:33:39 24 arri -- arrived at. The --

09:33:45 25 MR. BLACKWELL: You mean 3M.

09:33:47 1 THE WITNESS: Yeah. 3M is unaware.

09:33:49 2 A. The -- the designation of the 0.2-micron
09:33:55 3 filter was generally treated as a specification or a
09:34:00 4 nomenclature to designate the filter, and that's the
09:34:05 5 way that that was treated.

09:34:07 6 Q. Okay. I noticed that your attorney just
09:34:09 7 corrected you and told you to say "3M" instead of "the
09:34:12 8 company."

09:34:12 9 MR. BLACKWELL: I object to that
09:34:13 10 characterization. I did not tell him to say it, I
09:34:15 11 asked him if that's what he meant.

09:34:17 12 Q. He just made -- okay. He just made a
09:34:19 13 suggestion. He just said "3M."

09:34:20 14 A. Well --

09:34:20 15 MR. BLACKWELL: Well to be clear for the
09:34:21 16 record, I asked you if that's what you meant.

17 A. And -- and I'll clarify --

09:34:24 18 Q. It's clear that we're both asking you
09:34:26 19 questions today, but --

09:34:27 20 A. Well I'll clarify that the -- the 505 was
09:34:29 21 designed at Augustine Medical and -- and continued to
09:34:33 22 be sold through Arizant during the Arizant days, and
09:34:38 23 so, you know, 3M acquired those -- that company, but
09:34:44 24 the original design decisions were made at Augustine
09:34:50 25 Medical.

35

09:34:50 1 Q. Okay. And -- and in other words, here's the
09:34:52 2 question I wanted to ask you about that, about that --
09:34:54 3 that suggestion or whatever it was, is that by making
09:34:58 4 a difference between "the company" and "3M," we can
09:35:00 5 say that 3M today may not have all of the knowledge
09:35:05 6 that its predecessor companies had. Is that -- is
09:35:08 7 that reasonable?

09:35:09 8 MR. BLACKWELL: Yeah. I object to that
09:35:10 9 as -- the form of the question as overly vague, overly
09:35:13 10 broad.

09:35:14 11 And answer it if you can.

09:35:16 12 MR. ASSAAD: Well let's stick to "object to
09:35:18 13 form" under the rules.

09:35:19 14 MR. BLACKWELL: Well why don't you just
09:35:20 15 object for the record under the rules?

09:35:23 16 MR. ASSAAD: Just follow the rules, Jerry.

09:35:26 17 MR. BANKSTON: I mean -- yeah. I mean I'm
09:35:27 18 not really seeing any other reason to do it other than
09:35:28 19 the reason we both know you would do it, but maybe
09:35:29 20 like you could explain to me why you're stating bases
09:35:31 21 before I'm even asking for them. I don't --

09:35:33 22 Is that just different up here or something?
23 I don't --

09:35:35 24 And I'm literally asking. I really don't
09:35:36 25 know.

09:35:37 1 MR. BLACKWELL: If -- if you would like to
09:35:38 2 talk with me in the deposition, you can. However,
09:35:41 3 if I -- if I --

4 MR. BANKSTON: Well if you can -- it seems
09:35:43 5 like you're --

09:35:43 6 MR. BLACKWELL: May I finish, please?

09:35:44 7 MR. BANKSTON: Oh, sure. Go ahead.

09:35:45 8 MR. BLACKWELL: You asked me a question. If
09:35:46 9 I have a form objection to your question and if I may
09:35:48 10 state the basis for the form objection, you may choose
09:35:50 11 to try to clarify and correct it --

09:35:52 12 MR. BANKSTON: Okay.

09:35:52 13 MR. BLACKWELL: -- such that the record is
09:35:55 14 clear. That is the reason that I object as to form
09:35:57 15 and will give you a reason, such as vague, overly
09:35:59 16 broad, et cetera, because you may choose to rephrase
09:36:02 17 it to clarify your record.

18 MR. BANKSTON: All right. I -- I mean,
09:36:04 19 again, the only reason I was asking you is different
09:36:07 20 places do it different ways, and so -- I'm -- I'm a
09:36:09 21 visitor here so I just don't know.

09:36:10 22 MR. BLACKWELL: I am fine if you would like
09:36:13 23 for form objections to simply say "Objection to form,"
09:36:14 24 and we can simply take it up with the court at the
09:36:16 25 appropriate time. I don't have to give a reason. I

09:36:18 1 gave it for purposes of advising you in case you
09:36:21 2 wanted to rephrase your question.

09:36:23 3 MR. BANKSTON: Okay. Yeah, I'll be fine
09:36:27 4 with "Form" for this deposition.

09:36:27 5 MR. BLACKWELL: That will be fine.

09:36:28 6 MR. BANKSTON: Okay.

09:36:28 7 BY MR. BANKSTON:

09:36:33 8 Q. Let's go back to the question I was asking
09:36:35 9 you, which is: You'll agree with me that 3M today
09:36:41 10 does not have all of the information and knowledge
09:36:44 11 that its predecessor companies once possessed.

09:36:50 12 A. Well do you mean with respect to the design
09:36:52 13 of the 505 or the 700?

09:36:54 14 Q. Sure. We can -- we can go that specific if
09:36:56 15 you want to. Right. The --

09:36:57 16 Let's say there's a knowledge base regarding
09:36:58 17 the design of the 505. 3M today does not possess all
09:37:02 18 of the knowledge that its predecessor companies
09:37:04 19 possessed on that issue.

09:37:05 20 MR. BLACKWELL: I object to the form of the
09:37:06 21 question.

09:37:08 22 A. Well I mean I'll try to answer it as best I
09:37:12 23 am able. The -- the design requirements
09:37:15 24 specifications --

09:37:15 25 So the FDA requires a design practice to be

09:37:22 1 documented, so design requirements are documented,
09:37:26 2 design specifications, the testing involved in making
09:37:29 3 sure all those specifications are met, and a whole
09:37:33 4 series of activities that are noted and signed and
09:37:41 5 dated, so there's -- there's a -- there's a trail
09:37:44 6 of -- of the people involved in making decisions, and
09:37:48 7 the -- the reasons for those decisions are all
09:37:52 8 documented. So 3M certainly has all of that
09:37:54 9 information available to it in the design history and
09:38:00 10 design -- design history file, so all of that is
09:38:02 11 available to 3M, all of that knowledge is there.

09:38:07 12 Q. Okay. Let's -- let's revisit a question
09:38:09 13 that I had asked before, which is -- and to make sure
09:38:13 14 I understand your testimony is I had asked about how
09:38:16 15 was the decision made to arrive at the 505 filtration
09:38:20 16 efficiency, and I -- my -- what I took from that is
09:38:23 17 that today, currently, 3M doesn't know how that was
09:38:25 18 arrived at at Augustine Medical. Is that accurate or
09:38:28 19 not?

09:38:28 20 A. I believe that the design requirements
09:38:34 21 specification would contain information regarding the
09:38:38 22 selection of filters for the -- for the device.

09:38:41 23 Q. Okay.

09:38:41 24 A. Now I don't have that available nor did I
09:38:44 25 study it down at that level for this testimony.

09:38:47 1 Q. Okay. When you say you don't have that
09:38:49 2 available, what does that mean?

09:38:50 3 A. I mean I don't have it available, with me
09:38:52 4 today.

09:38:53 5 Q. Okay. Are those --

09:38:53 6 A. Those documents are available to 3M. Those
09:38:56 7 are required documents to be kept. The FDA requires
09:39:01 8 those documents to be kept in a -- as long as the
09:39:07 9 product is being sold.

09:39:08 10 Q. But --

09:39:08 11 So as far as the decisions regarding the
09:39:13 12 selection of the filter medium and its level of
09:39:16 13 efficiency, that's not something you're prepared to
09:39:19 14 talk about today.

09:39:20 15 MR. BLACKWELL: I object to the form of the
09:39:21 16 question, and assumes facts.

09:39:24 17 A. Again, the -- the -- the decision to use a
09:39:27 18 certain -- or to specify and then use a certain level
09:39:31 19 of filtration would have been documented in the design
09:39:36 20 requirements specifications for the product, --

09:39:38 21 Q. Uh-huh.

09:39:40 22 A. -- so that information does exist.

09:39:42 23 Q. Okay.

09:39:44 24 A. I -- I don't know who made those decisions.

09:39:46 25 Q. Okay. So we --

09:39:49 1 There is documented information about the
09:39:51 2 selection and decision regarding the filter medium and
09:39:54 3 its efficiency with the 505, but that is not
09:39:57 4 information you have seen preparing for this
09:39:58 5 deposition.

09:39:59 6 A. That is correct.

09:40:00 7 Q. Okay. As far as the --

09:40:16 8 Just to call back, remember we were
09:40:18 9 discussing about the 505, it had a cylindrical filter?

09:40:22 10 A. Yes.

09:40:22 11 Q. And there could be different shapes for
09:40:24 12 filters in other units.

09:40:25 13 A. And -- and there -- and there are.

09:40:27 14 Q. Okay.

09:40:27 15 A. Uh-huh.

09:40:28 16 Q. Who at 3M -- or excuse me. Again here I
09:40:31 17 almost slipped up and did it, but I'll correct myself.

09:40:34 18 Who at Augustine Medical would have been
09:40:35 19 responsible for the physical design, the shape, and
09:40:37 20 configuration of the filter?

09:40:39 21 A. The person?

09:40:41 22 Q. Sure.

09:40:42 23 A. Probably Randy Arnold --

09:40:44 24 Q. Okay.

09:40:45 25 A. -- I would guess.

09:40:47 1 MR. BLACKWELL: Are you guessing?

09:40:48 2 THE WITNESS: I'm guessing.

09:40:49 3 MR. BLACKWELL: You're not required to

09:40:51 4 guess.

09:40:51 5 THE WITNESS: Okay.

09:40:52 6 MR. BLACKWELL: So you speak to what you

09:40:54 7 know.

09:41:03 8 Q. Now let's talk a little bit about the second

09:41:07 9 filter, what we've referred to as the -- the second

09:41:11 10 media used in the 505, and I believe you told me this

09:41:15 11 was sometime in the 2000s, that time period.

09:41:17 12 A. I believe that's correct.

09:41:18 13 Q. Okay. I understand what the impetus for

09:41:22 14 having the change made was, but now my question is:

09:41:25 15 When you knew that you could no longer use the M10

09:41:31 16 fil -- filter media as it was being configured by

09:41:33 17 Porous Media, when that was no longer an option, I

09:41:37 18 take it there was then a decision made to use a

09:41:39 19 different filter.

09:41:40 20 A. A -- a different filter media.

09:41:42 21 Q. Okay.

09:41:43 22 A. The filter was physically exactly the same

09:41:45 23 size.

09:41:45 24 Q. Okay. Let's -- let's talk -- step back for

09:41:49 25 a minute and talk about what a filter is. And, for

09:41:54 1 example, with the 505, you have a cylindrical object
09:41:57 2 that you would call the filter; correct?

09:41:59 3 A. Yes.

09:41:59 4 Q. Okay. Let's talk about the various parts of
09:42:01 5 that filter. I assume it has some sort of housing,
09:42:04 6 some sort of basic plastic design that encases the
09:42:07 7 unit.

09:42:08 8 A. That's correct.

09:42:08 9 Q. Okay. And we know it has a filter medium;
09:42:11 10 correct?

09:42:11 11 A. Yes.

09:42:11 12 Q. A medium would be a pleated material which
09:42:14 13 the air passes through.

09:42:15 14 MR. BLACKWELL: I object to the form of the
09:42:16 15 question.

09:42:18 16 A. In that filter, yes, it's pleated.

09:42:20 17 Q. Okay. What other parts of the filter might
09:42:23 18 there be?

09:42:24 19 A. There's a --

09:42:25 20 There are screens that prevent ignition --
09:42:30 21 fire from spreading, there's a screen on the external
09:42:36 22 surface of the filter to capture very large particles
09:42:40 23 before they impinge on the filter surface, and then
09:42:46 24 there are caps just to make the whole unit airtight.

09:42:52 25 Q. When there was a change made in terms of

09:42:55 1 filter medium, is the -- is the -- the media that was
09:43:00 2 used the only thing that was changed during that
09:43:02 3 design change?

09:43:03 4 A. To my knowledge.

09:43:04 5 Q. Okay. Now there was a decision made to
09:43:14 6 change to a different media and choose a level of
09:43:16 7 filtration for that new media. Do you know who was
09:43:19 8 responsible for making that decision?

09:43:20 9 A. I don't know personally who was responsible
09:43:24 10 for that, but there certainly is an ECO documenting
09:43:28 11 that change.

09:43:28 12 Q. Okay. Have you reviewed that ECO?

09:43:30 13 A. I have seen that ECO.

09:43:31 14 Q. Okay. Does that ECO document the reasons,
09:43:39 15 rationale, or justification for the new level of
09:43:42 16 efficiency in the filter?

09:43:44 17 A. The reason for changing the filter media had
09:43:48 18 to do with the inability of Porous Media to obtain the
09:43:54 19 original media.

09:43:57 20 Q. Okay. And so when that happened, it
09:44:00 21 basically becomes a wide open game now; right? You
09:44:02 22 could -- you could potentially put any kind of filter
09:44:05 23 on the device, assuming you could make it work; right?

09:44:08 24 MR. BLACKWELL: I object to the form of the
09:44:09 25 question.

44

09:44:09 1 A. Well I mean that's an engineering question.

09:44:12 2 I mean there are more --

09:44:14 3 There are many things to consider when

09:44:17 4 replacing the filter.

09:44:18 5 Q. Okay. So, for instance, let me just walk us

09:44:22 6 through this process, this design process. The

09:44:24 7 company understands that the filter is not going to be

09:44:27 8 able -- you're not going to be able to get the same

09:44:31 9 M10 filter from Porous Media any more. We know that's

09:44:34 10 the situation. Going forward, there could have been

09:44:36 11 other possibilities, vendors, suppliers, other filters

09:44:39 12 in the world that would have provided more, same, or

09:44:41 13 less efficiency as the M10 filter; correct?

09:44:44 14 MR. BLACKWELL: I object to the form of the

09:44:45 15 question.

09:44:47 16 A. I suspect that that's correct. I -- I

09:44:49 17 wasn't involved in selecting vendors for that, so --

09:44:52 18 but I'm -- I --

09:44:54 19 It wouldn't surprise me to learn that there

09:44:56 20 are other vendors making filter media.

09:44:57 21 Q. Right. We know there are filter companies

09:44:59 22 in the world.

09:45:00 23 A. Yes.

09:45:00 24 Q. And we know there's a wide range of filter

09:45:03 25 efficiencies in the world.

09:45:04 1 A. Yes.

09:45:04 2 Q. And you have it all the way down to a MERV 1
09:45:07 3 filter, that just prevents large particles, all the
09:45:10 4 way up to a HEPA filter; correct?

09:45:12 5 A. That's correct.

09:45:13 6 Q. Okay. When the old filter in the 505 was no
09:45:17 7 longer available, there was a broad range of choices
09:45:20 8 for what could be put into the unit, and so what I'm
09:45:23 9 asking is: In that ECO, is there any discussion for
09:45:26 10 the selection among that broad range of filters for
09:45:30 11 why the M20 filter was selected?

09:45:34 12 A. I --

09:45:35 13 Not to my recollection.

09:45:36 14 Q. Okay. Outside the ECO in general, can you
09:45:41 15 tell me why the company chose the filtration level it
09:45:45 16 did for the replacement filter?

09:45:47 17 A. Well I -- the --

09:45:53 18 As I mentioned before, there are other
09:45:56 19 considerations in the design of a filter, and one of
09:45:59 20 those is the pressure drop across the filter. The
09:46:03 21 performance of the warming unit is -- is a
09:46:07 22 substantially important design requirement, and to
09:46:10 23 meet that we have to have a pressure drop that isn't
09:46:16 24 exceedingly high, and so one of the major factors that
09:46:20 25 went into selecting the filter media was a desire to

09:46:25 1 keep the pressure drop as low as possible to keep the
09:46:28 2 performance of the system high.

09:46:30 3 Q. Okay. So the original filter on the model
09:46:35 4 505 had an acceptable pressure drop from the company's
09:46:37 5 perspective.

09:46:38 6 A. Yes.

09:46:38 7 Q. Okay. And then when the new prototype of
09:46:41 8 that same type of filter media was made, it had an
09:46:44 9 unacceptable pressure drop; is that correct?

09:46:45 10 A. No. I -- I don't -- I'm not --

09:46:52 11 Q. Okay.

09:46:53 12 A. Maybe I'm misunderstanding your question,
09:46:55 13 but no.

09:46:55 14 Q. Sure. Okay. So when Porous Media announced
09:46:58 15 to the company, "We are no longer going to be able to
09:47:00 16 provide you the same M10 filter that we provided
09:47:03 17 before," did Porous Media provide you with any
09:47:07 18 potential alternative filters to use?

09:47:08 19 A. I don't know for a fact that they did that.

09:47:14 20 Q. Okay. Did you --

09:47:15 21 Have you talked to anybody at Porous Media?

09:47:17 22 A. I have not.

09:47:18 23 Q. Have you talked to anybody at, now as
09:47:21 24 they're known, Pentair?

09:47:21 25 A. No, I have not.

09:47:22 1 Q. Okay. Have you spoken to anybody who was
09:47:25 2 involved in those decisions with Porous Media about
09:47:27 3 filter prototyping?

09:47:28 4 A. No, I have -- I have only looked at the ECOs
09:47:31 5 surrounding the change in the filter.

09:47:35 6 Q. And those ECOs don't contain the information
09:47:37 7 that I'm asking you about in these questions; correct?

09:47:40 8 A. They do contain information regarding
09:47:43 9 pressure drop of the new filter media.

09:47:45 10 Q. Okay. Of the pressure --

09:47:47 11 So when we talk about pressure drop of the
09:47:50 12 new filter media, we're talking about the pressure
09:47:52 13 drop that was achieved with the use of the M20 filter
09:47:56 14 media.

09:47:56 15 A. Yes.

09:47:57 16 Q. Okay. And in other words, in that ECO it
09:47:59 17 documents that the pressure drop produced by the M20
09:48:02 18 filter media was acceptable to the company in terms of
09:48:05 19 airflow of the unit.

09:48:06 20 A. Yes.

09:48:07 21 Q. Okay. Now do you know if the company did
09:48:12 22 anything to explore whether there was filters of the
09:48:16 23 same rough equivalent filtration efficiency as the M10
09:48:20 24 media that had been used that could achieve an
09:48:22 25 acceptable pressure drop?

09:48:23 1 A. I do not know that -- whether that was done.
09:48:27 2 It's not indicated on the ECO.

09:48:28 3 Q. Okay. Would -- would it be fair to say that
09:48:32 4 any design decisions, discussions, information to the
09:48:39 5 company that wasn't contained in that ECO is not
09:48:42 6 something in terms of filter design decisions you can
09:48:45 7 talk about today?

09:48:45 8 MR. BLACKWELL: I object to the form of the
09:48:46 9 question.

09:48:54 10 A. Well as I -- as I mentioned before, the --
09:48:57 11 the thing that I am uncertain about is whether
09:49:01 12 alternate filter media was investigated as being
09:49:05 13 suitable for replacement.

09:49:07 14 Q. Okay. I want to go back to the original
09:49:13 15 500 -- 505 filter, this M10 filter that was released
09:49:17 16 on the unit when it was first sold. Can you tell me
09:49:20 17 what was done to provide some sort of safety
09:49:23 18 validation that that filter would achieve its intended
09:49:28 19 purpose as a -- as a safety -- as a safety function?

09:49:31 20 MR. BLACKWELL: Object to the form of the
09:49:32 21 question, and assuming facts also.

09:49:35 22 A. So --

09:49:37 23 Q. Well let me clear up that objection because
09:49:40 24 I think there's something I need to clear up about
09:49:42 25 that.

1 A. Okay.

09:49:42 2 Q. The filter plays a safety function; right?

09:49:44 3 MR. BLACKWELL: Object as asked and

09:49:46 4 answered, but you can go ahead.

09:49:46 5 A. Well again, I think that the filter serves

09:49:50 6 two purposes: one is to prevent the fouling of the

09:49:52 7 internal components of the warming unit; and the other

09:49:55 8 is to minimize the amount of particulates that are

09:49:59 9 exhausted into the -- into the blanket.

09:50:01 10 Q. And that's a safety function; correct?

09:50:03 11 A. We -- we could view that as a safety

09:50:06 12 function.

09:50:06 13 Q. Okay. When the 505 was being validated in

09:50:11 14 its design, can you tell me what safety validation was

09:50:14 15 done with respect to the filter?

09:50:15 16 A. I do not believe that any particulate

09:50:20 17 filtration efficiency studies were completed at that

09:50:24 18 time.

09:50:24 19 Q. Okay.

09:50:28 20 A. And I should just point out, I guess

09:50:30 21 quickly, that the -- the filter media in the 505 was

09:50:35 22 again designated as 0.2-micron level. The filters

09:50:42 23 that were in the previous warming units, the previous

09:50:44 24 model 200s and the 250s and the 275s, were somewhere

09:50:50 25 around two microns, so 10 times less efficient or

09:50:55 1 effective in terms of their filtration effectiveness.

09:51:00 2 Q. Do you know offhand just from your own
09:51:02 3 personal knowledge if that's one of the reasons those
09:51:04 4 units are not suitable for use in operating rooms?

09:51:07 5 A. That's not --

09:51:08 6 MR. BLACKWELL: I object as beyond the scope
09:51:09 7 of the 30(b)(6) notice.

09:51:11 8 You can answer.

09:51:11 9 A. That's not the reason.

09:51:12 10 Q. Okay.

09:51:13 11 A. The reason that those units are not used in
09:51:15 12 operating rooms has to do with the high temperature of
09:51:20 13 the nozzle -- of the air leaving the nozzle of the
09:51:22 14 unit, not the filtration.

09:51:23 15 Q. Okay. When I asked about safety validation,
09:51:30 16 you had told me that a certain type of particulate
09:51:32 17 testing had not been performed, and --

09:51:36 18 A. To my knowledge.

09:51:37 19 Q. Correct.

09:51:38 20 -- and I want to make sure that we're
09:51:39 21 talking --

09:51:40 22 I understand that's one example of something
09:51:42 23 that could be done in terms of validation, but in
09:51:46 24 terms of anything under the sun, is it -- is it your
09:51:48 25 testimony today that there was no safety validation

09:51:50 1 for the 505's filter?

09:51:52 2 MR. BLACKWELL: I object to the form of the
09:51:54 3 question.

09:51:54 4 A. Well again, the -- to --

09:51:56 5 To my knowledge, and based on my review of
09:52:00 6 the records that I have available to me, I didn't see
09:52:03 7 any testing related to particulate efficiency of the
09:52:08 8 filter media.

09:52:08 9 Q. Okay. And so I take it by that same token
09:52:13 10 there was no biological testing of the filter.

09:52:20 11 MR. BLACKWELL: I object to the form of the
09:52:21 12 question.

09:52:22 13 A. I'm unaware --

09:52:23 14 The company is unaware of any biological
09:52:25 15 testing conducted on the -- during the design of the
09:52:31 16 505.

09:52:32 17 Q. Okay. Let's talk a little bit, then, about
09:52:44 18 the new media that comes into play, the M20 media that
09:52:48 19 was introduced sometime in the 2000s period. Can you
09:52:52 20 tell me: When that design change was made, what did
09:52:54 21 the company do to ensure it was safe for the patients
09:52:57 22 it would be used on?

09:52:59 23 A. Well the --

09:53:05 24 When the media was replaced, the design
09:53:09 25 requirements specifications were again reviewed to

09:53:11 1 make certain that the filter did not alter the -- in
09:53:17 2 any way the requirements for the manufacturing of
09:53:21 3 the -- of the device, so that was revalidated.

09:53:25 4 Q. Okay. When you talk about "requirements for
09:53:28 5 the manufacture of the device," what requirements are
09:53:30 6 you speaking of?

09:53:31 7 A. The device has to meet certain requirements
09:53:34 8 of airflow, of temperature, things -- things like
09:53:41 9 that, specifications that are contained in the design
09:53:44 10 requirements. There is a -- a standard method for
09:53:47 11 validating those characteristics of the warming unit.
09:53:54 12 To my knowledge there are no design requirements
09:54:00 13 specifications for a certain particulate level of
09:54:03 14 efficiency for the filter.

09:54:04 15 Q. Okay. Were those requirements created
09:54:06 16 internally at the company?

09:54:09 17 A. Which -- which requirements, --

09:54:10 18 Q. Your --

09:54:11 19 A. -- the design --

09:54:12 20 Q. The manufacturing requirements you're
09:54:13 21 speaking of right now, are they created internally or
09:54:16 22 are they imposed on the company from outside?

09:54:18 23 A. Those are created internally.

09:54:19 24 Q. Okay. When the decision was made and the
09:54:23 25 implementation was made of the M20 filter media, can

09:54:27 1 you tell me what was done to assure patient safety in
09:54:32 2 terms of airborne contamination?

09:54:35 3 A. Well we had -- we had a large number of
09:54:38 4 clinical studies that had been done at that point that
09:54:43 5 indicated that there was no increased risk of
09:54:47 6 surgical-site infection when the Bair Hugger units
09:54:51 7 were used, and this is with filter media that -- that
09:54:56 8 was probably on the order of 10 times less effective
09:54:58 9 than the M20 media that was subsequently selected.

09:55:03 10 Q. Okay. What -- what clinical studies are you
09:55:05 11 referring to?

09:55:06 12 A. Hall, Hall and Teenier, Zink, Avidan. I
09:55:18 13 mean there are -- there are a number of studies that
09:55:19 14 we have available in our bibliography that -- that
09:55:24 15 we've reviewed as indicating that the -- the risks to
09:55:32 16 patients, given the filtration level that we had
09:55:35 17 selected, was -- were -- were very low.

09:55:38 18 Q. [REDACTED]
09:55:49 19 [REDACTED]
09:55:52 20 [REDACTED]
09:55:56 21 [REDACTED]
09:56:00 22 [REDACTED]
09:56:03 23 [REDACTED]
09:56:06 24 [REDACTED] [REDACTED]
09:56:08 25 [REDACTED]

			54
09:56:11	1	[REDACTED]	
09:56:15	2	[REDACTED]	
09:56:15	3	[REDACTED] [REDACTED]	
09:56:16	4	[REDACTED] [REDACTED] [REDACTED]	
09:56:17	5	[REDACTED]	
09:56:20	6	[REDACTED]	
09:56:22	7	[REDACTED] [REDACTED]	
09:56:24	8	[REDACTED]	
09:56:26	9	[REDACTED] [REDACTED]	
09:56:26	10	[REDACTED] [REDACTED] [REDACTED]	
09:56:29	11	[REDACTED]	
09:56:30	12	[REDACTED] [REDACTED]	
09:56:33	13	[REDACTED]	
09:56:34	14	[REDACTED] [REDACTED] [REDACTED]	
09:56:36	15	[REDACTED] [REDACTED]	
09:56:40	16	[REDACTED]	
09:56:43	17	[REDACTED]	
09:56:44	18	[REDACTED]	
09:56:45	19	[REDACTED] [REDACTED]	
09:56:45	20	[REDACTED] [REDACTED]	
09:56:45	21	[REDACTED]	
09:56:46	22	[REDACTED] [REDACTED]	
09:56:47	23	[REDACTED]	
09:56:48	24	[REDACTED] [REDACTED]	
09:56:49	25	[REDACTED] [REDACTED] [REDACTED]	

			55
09:56:51	1	[REDACTED]	[REDACTED]
09:56:53	2	[REDACTED]	[REDACTED]
09:56:56	3	[REDACTED]	[REDACTED]
09:56:59	4	[REDACTED]	[REDACTED]
09:57:02	5	[REDACTED]	[REDACTED]
09:57:07	6	[REDACTED]	[REDACTED]
09:57:08	7	[REDACTED]	[REDACTED]
09:57:10	8	[REDACTED]	[REDACTED]
09:57:14	9	[REDACTED]	[REDACTED]
09:57:17	10	[REDACTED]	[REDACTED]
09:57:18	11	[REDACTED]	[REDACTED]
09:57:25	12	[REDACTED]	[REDACTED]
09:57:28	13	[REDACTED]	[REDACTED]
09:57:32	14	[REDACTED]	[REDACTED]
09:57:35	15	[REDACTED]	[REDACTED]
09:57:44	16	[REDACTED]	[REDACTED]
09:57:50	17	[REDACTED]	[REDACTED]
09:57:54	18	[REDACTED]	[REDACTED]
09:57:55	19	[REDACTED]	[REDACTED]
09:57:57	20	[REDACTED]	[REDACTED]
09:57:58	21	[REDACTED]	[REDACTED]
09:57:58	22	[REDACTED]	[REDACTED]
09:58:01	23	[REDACTED]	[REDACTED]
09:58:09	24	[REDACTED]	[REDACTED]
09:58:13	25	[REDACTED]	[REDACTED]

			56
09:58:17	1	[REDACTED]	
09:58:21	2	[REDACTED]	
09:58:24	3	[REDACTED]	
09:58:26	4	[REDACTED] [REDACTED]	
09:58:27	5	[REDACTED]	
09:58:29	6	[REDACTED] [REDACTED]	
09:58:31	7	[REDACTED]	
09:58:34	8	[REDACTED]	
09:58:37	9	[REDACTED]	
09:58:41	10	[REDACTED]	
09:58:43	11	[REDACTED]	
09:58:47	12	[REDACTED]	
09:58:50	13	[REDACTED]	
09:58:54	14	[REDACTED]	
09:59:01	15	[REDACTED]	
09:59:05	16	[REDACTED]	
09:59:11	17	[REDACTED]	
09:59:12	18	[REDACTED]	
09:59:13	19	[REDACTED] [REDACTED]	
09:59:16	20	[REDACTED]	
09:59:20	21	[REDACTED]	
09:59:21	22	[REDACTED] [REDACTED] [REDACTED]	
09:59:26	23	[REDACTED]	
09:59:29	24	[REDACTED]	
09:59:34	25	[REDACTED]	

09:59:38 1 [REDACTED]

09:59:39 2 [REDACTED]

10:00:04 3 [REDACTED]

10:00:09 4 [REDACTED]

10:00:15 5 [REDACTED]

10:00:20 6 [REDACTED]

10:00:20 7 [REDACTED]

10:00:21 8 [REDACTED]

10:00:29 9 [REDACTED]

10:00:33 10 [REDACTED]

10:00:37 11 [REDACTED]

10:00:39 12 [REDACTED]

10:00:40 13 [REDACTED]

10:00:40 14 [REDACTED]

10:00:49 15 Q. Let me just repeat it then. Let's -- let's

10:00:52 16 rephrase this a different way. If -- if something's

10:00:54 17 going to be changed on the Bair Hugger --

10:00:56 18 Let's take a really simple example. The

10:00:59 19 original Bair Hugger 505 was white; right?

10:01:01 20 A. Yes.

10:01:04 21 Q. Okay. Let's say you want to make it blue

10:01:05 22 and just have the casing change color. That obviously

10:01:10 23 is not going to have significant impact on the

10:01:11 24 performance of the unit; right?

10:01:13 25 A. One would not expect it to.

10:01:15 1 Q. In other words, that's the kind of change
10:01:17 2 that would not require any special validation or any
10:01:21 3 lengthy discussion really; correct?

10:01:23 4 A. It de -- it depends. If there --

10:01:26 5 Sometimes colors do have an effect on the
10:01:30 6 molding properties of materials and things like that.
10:01:33 7 So there would normally be a group convened to make
10:01:38 8 certain that any change that's being made to the
10:01:41 9 device still allows the device to meet its design
10:01:45 10 requirements specifications. This is a requirement of
10:01:48 11 the quality system in place -- that's in place and is
10:01:53 12 a requirement of FDA regulations.

10:01:55 13 Q. I'm glad I asked you that. I learned
10:01:56 14 something today because I would never have thought a
10:01:58 15 change in the color could have an impact. But even
10:02:00 16 something that simple --

10:02:01 17 A. Of course.

10:02:01 18 Q. -- may -- you may need to convene people and
10:02:04 19 discuss it.

10:02:05 20 MR. BLACKWELL: Yeah. Object and move to
10:02:06 21 strike the narrative.

10:02:07 22 You can go ahead.

10:02:08 23 A. Yes.

10:02:08 24 Q. Okay. So, for instance, in terms of the
10:02:11 25 change of a filter, that's obviously something you're

10:02:14 1 also going to want to convene a group together and

10:02:17 2 talk about before the change is made; correct?

10:02:18 3 MR. BLACKWELL: Object to the form of the

10:02:20 4 question.

10:02:20 5 A. Well again, changing the filter would have

10:02:24 6 triggered a review to make certain that the design

10:02:28 7 requirements specifications for the device were not

10:02:31 8 altered in -- in a way that would put them outside of

10:02:35 9 those specifications.

10:02:36 10 [REDACTED]

10:02:39 11 [REDACTED]

10:02:41 12 [REDACTED]

10:02:43 13 [REDACTED]

10:02:44 14 [REDACTED]

10:02:49 15 [REDACTED]

10:02:56 16 [REDACTED]

10:02:58 17 [REDACTED]

10:03:03 18 [REDACTED]

10:03:08 19 [REDACTED]

10:03:11 20 [REDACTED]

10:03:16 21 [REDACTED]

10:03:16 22 [REDACTED]

10:03:17 23 [REDACTED]

10:03:17 24 [REDACTED]

10:03:21 25 [REDACTED]

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10:04:38	22	[REDACTED]	
10:04:40	23	[REDACTED]	
10:04:46	24	[REDACTED]	
10:04:48	25	[REDACTED]	

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10:04:49 1 [REDACTED]

10:04:51 2 [REDACTED]

10:04:54 3 [REDACTED]

10:04:56 4 [REDACTED]

10:04:57 5 [REDACTED] [REDACTED]

10:04:58 6 Q. Okay. So I understand that there was a part

10:05:00 7 done to validate that the device was performing as you

10:05:03 8 wanted it to in terms of pressure drop and airflow.

10:05:07 9 Is -- is that really what that validation was about?

10:05:10 10 Am I understanding that correctly?

10:05:11 11 A. Well that was the validation that I saw that

10:05:16 12 was associated with that ECO.

10:05:17 13 Q. Okay. But in terms of the prevention of

10:05:22 14 airborne contamination, was anything specifically done

10:05:26 15 in terms of safety validation for that design change?

10:05:30 16 A. In -- internally at the time Augustine did

10:05:34 17 not have the ability to test that sort of thing, so we

10:05:39 18 relied on vendors to -- to do that sort of work for

10:05:44 19 us.

10:05:44 20 Q. Okay. And I think I just want to make sure

10:05:46 21 I have it clear here. We're -- we're talking about

10:05:49 22 the M20 replacement media that went into the Bair

10:05:54 23 Hugger 505 unit.

10:05:55 24 A. Yes.

10:05:55 25 Q. Okay. And -- and your testimony is that

10:05:58 1 Augustine was responsible for that.

10:06:04 2 A. So Augustine, the company, was the company

10:06:08 3 in charge at the time the filter media was changed.

10:06:11 4 That -- that is correct.

10:06:13 5 Q. Okay. So I guess the testimony would be

10:06:24 6 Augustine Medical and Arizant had different validation

10:06:29 7 recordkeeping practices; is that --

10:06:33 8 A. No.

10:06:33 9 Q. Okay.

10:06:33 10 A. They were the same.

10:06:34 11 Q. Okay. So what was it that August --

10:06:38 12 So I'm trying to understand your -- your

10:06:40 13 answer about Augustine Medical not having procedures

10:06:42 14 in place. What did they --

10:06:44 15 A. No, not procedures, just not the capability,

10:06:46 16 the scien -- the test fixtures to do that sort of

10:06:51 17 testing related to filter efficiency.

10:06:54 18 Q. Okay.

10:06:55 19 A. For that we relied on vendors. I mean there

10:06:59 20 were many components that we don't -- didn't have

10:07:03 21 internal capabilities of -- of validating or -- or

10:07:08 22 confirming, and so we rely on vendors to meet certain

10:07:12 23 specifications.

10:07:13 24 Q. Okay. So with respect to any safety

10:07:15 25 validation done with respect to airborne contamination

10:07:19 1 and the change of that filter medium, that would have
10:07:22 2 been conducted outside the company.

10:07:25 3 A. The filter efficiency testing would have
10:07:29 4 been conducted outside the company.

10:07:30 5 Q. Well I don't want to -- I don't want to
10:07:32 6 restrict myself that -- and I'm --

10:07:34 7 I want to talk about anything under the sun
10:07:36 8 that could qualify as safety validation for airborne
10:07:38 9 contamination. Was all of that done outside of the
10:07:41 10 company?

10:07:42 11 MR. BLACKWELL: I object to the form of the
10:07:43 12 question.

10:07:47 13 A. To -- to my knowledge there was -- there was
10:07:52 14 no internal testing for particulate safety validation.

10:07:56 15 Q. Okay. And -- and I understand nothing was
10:08:01 16 done internally. I'm -- I'm asking was anything that
10:08:04 17 was done done externally?

10:08:07 18 A. Well again, we --

10:08:10 19 There are numerous studies, confirmatory
10:08:14 20 studies done by -- in a -- in a clinical setting that
10:08:20 21 confirmed that the risk to patients was the same or
10:08:28 22 equiv -- equivalent to what it was in the -- with the
10:08:32 23 previous filter medium.

10:08:35 24 Q. There are -- there are clinical studies
10:08:37 25 comparing the previous filter media to the current

10:08:39 1 filter media in the 505?

10:08:41 2 A. Not specifically, no. My -- my point is
10:08:44 3 that there were studies done subsequent to the change
10:08:47 4 in the filter media that confirmed that the
10:08:52 5 particulate loads were the -- were the same or -- or
10:08:56 6 equivalent to what they were before the filter was
10:08:58 7 changed.

10:08:59 8 Q. Now that wouldn't be --

10:09:00 9 A. Or the risk to the patient, sorry, was the
10:09:02 10 same.

10:09:02 11 Q. Okay. Now if we're talking about studies
10:09:05 12 that were done after the product was already released
10:09:06 13 and sold on the market, that wouldn't be design
10:09:08 14 validation; would it?

10:09:09 15 A. No. Those are studies that are conducted by
10:09:14 16 independent clinical investigators.

10:09:17 17 Q. Okay. And in other words, because they did
10:09:20 18 not occur before the Bair Hugger was put on the
10:09:22 19 market, they could not have been used to validate the
10:09:25 20 design of the product; correct?

10:09:28 21 MR. BLACKWELL: I object to the form of the
10:09:29 22 question.

10:09:31 23 A. Well, and -- and they weren't used to
10:09:33 24 validate the product.

10:09:34 25 Q. Okay. So again, my question relates to what

10:09:37 1 was done externally to the company to validate the
10:09:40 2 filter change in terms of airborne contamination.

10:09:44 3 A. Well prior to the release of the product I'm
10:09:47 4 not aware of -- of anything related to this -- to the
10:09:52 5 safety topic that was done outside of the company.

10:09:54 6 Q. Okay. Let's talk a little bit about the
10:10:06 7 Bair Hugger 750. And -- and let's first -- the Bair
10:10:12 8 Hugger 750 --

10:10:13 9 MR. BLACKWELL: Is this a good time to take
10:10:14 10 a --

10:10:15 11 MR. BANKSTON: Yeah, sure, since we're
10:10:17 12 switching topics. Yeah, absolutely.

10:10:19 13 THE REPORTER: Off the record, please.

10:22:57 14 (Recess taken.)

10:22:57 15 BY MR. BANKSTON:

10:22:58 16 Q. Where we had just dropped off, we had just
10:23:01 17 started talking about the model 750. And the
10:23:04 18 development period for the 750, that occurred when the
10:23:07 19 company was Augustine Medical; correct?

10:23:08 20 A. Yes.

10:23:09 21 Q. Okay. The model 750 is -- has some
10:23:16 22 differences from the model 500. There's been some
10:23:20 23 changes made to the unit.

10:23:20 24 A. Oh, yes.

10:23:21 25 Q. Okay. In fact, the 750 was an effort to

10:23:23 1 improve on the model 505; correct?

10:23:25 2 A. In some ways.

10:23:26 3 Q. Okay. And one of those changes that I want
10:23:32 4 to talk about is there is a --

10:23:38 5 The filter on the model 750 is different
10:23:40 6 than the one that was initially released on the model
10:23:43 7 505.

10:23:43 8 A. Well the -- the -- the physical filter
10:23:47 9 design is -- is substantially different than the 505.

10:23:50 10 Q. Uh-huh.

10:23:51 11 A. Yes.

10:23:52 12 Q. And they're -- they're different shapes and
10:23:55 13 sizes; correct?

10:23:56 14 A. That's correct.

10:23:56 15 Q. Okay. The media within the two filters are
10:23:58 16 also different.

10:23:59 17 A. Yes.

10:24:00 18 Q. Okay. Now do you know the date at which the
10:24:05 19 model 750 went onto the market for sale?

10:24:08 20 A. The exact date I -- I don't recall as I'm
10:24:12 21 sitting here, but it was 2001, 2002, --

10:24:15 22 Q. Okay.

10:24:15 23 A. -- somewhere around there.

10:24:16 24 Q. Right about at that time period, 2002, there
10:24:21 25 was a Bair Hugger 505 being sold by the company.

10:24:25 1 A. Yes.

10:24:26 2 Q. It was still being sold.

10:24:29 3 And there was a model 750 being sold by the
10:24:32 4 company as well.

10:24:32 5 A. In 2002, yes.

10:24:35 6 Q. And those --

10:24:37 7 At that time those two units had different
10:24:39 8 filter media.

10:24:40 9 A. That --

10:24:40 10 I believe that is correct.

10:24:41 11 Q. Okay. Now the model 750, that unit had the
10:24:46 12 M20 media we've been discussing; correct?

10:24:48 13 A. Yes.

10:24:49 14 Q. Okay. So in terms of time, the 750 was
10:24:53 15 introduced with the M20 media before the change was
10:24:56 16 made to the model 505.

10:24:58 17 A. I believe that is correct.

10:25:00 18 Q. Okay. In other words, the model 750 was the
10:25:05 19 first time that the company had integrated the M20
10:25:10 20 media into a product for sale.

10:25:13 21 A. I believe that's correct, but I'd -- I'd
10:25:16 22 have to look at an ECO to make absolutely certain of
10:25:19 23 that fact.

10:25:19 24 Q. The model 750 has a different air-output
10:25:35 25 specification and different filter density than the

10:25:38 1 model 505.

10:25:41 2 A. Density? I'm not certain of -- about the
10:25:44 3 density question. However, the airflow is higher in
10:25:47 4 the model 750.

10:25:50 5 Q. Okay. With respect to density, do you --
10:25:55 6 are you familiar with any testing that was done to
10:25:58 7 determine the different densities between the M10 and
10:26:03 8 M20 media?

10:26:04 9 A. I'm not aware of any testing that was done
10:26:08 10 internally to measure density. However, I am aware
10:26:12 11 that testing was done to look at pressure drop across
10:26:14 12 the filter during the design --

10:26:16 13 Q. Okay.

10:26:16 14 A. -- and subsequently.

10:26:17 15 Q. You would agree with me that the M20 media
10:26:27 16 produces far less of a pressure drop than the M10
10:26:30 17 media does.

10:26:33 18 A. I -- I don't know for a fact if that's true.
10:26:36 19 I do know that, in the physical shape that the filters
10:26:40 20 are in, that the pressure drop in the 750 was adequate
10:26:46 21 to produce the airflow that was desired.

10:26:49 22 Q. Okay. Now when the 750 was first being
10:26:58 23 developed and the design decisions were made for the
10:27:02 24 filter, do you know what the target efficiency for
10:27:05 25 that filter was going to be?

10:27:08 1 A. The -- at the -- at the --
10:27:10 2 Originally, it was going to be a HEPA
10:27:11 3 filter.

10:27:12 4 [REDACTED]

10:27:16 5 [REDACTED]

10:27:16 6 [REDACTED]

10:27:19 7 [REDACTED]

10:27:25 8 [REDACTED]

10:27:28 9 [REDACTED]

10:27:31 10 [REDACTED]

10:27:35 11 [REDACTED]

10:27:41 12 [REDACTED]

10:27:44 13 [REDACTED]

10:27:47 14 [REDACTED]

10:27:50 15 [REDACTED]

10:27:52 16 [REDACTED]

10:27:54 17 [REDACTED]

10:27:57 18 [REDACTED]

10:27:59 19 [REDACTED]

10:28:03 20 [REDACTED]

10:28:09 21 [REDACTED]

10:28:11 22 [REDACTED]

10:28:15 23 [REDACTED]






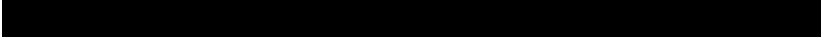
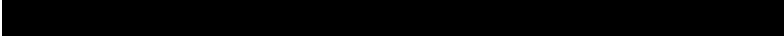
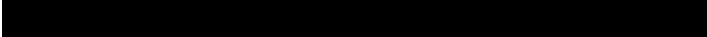



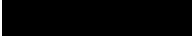

























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10:28:23 25 [REDACTED]

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10:33:54 1 [REDACTED]

10:33:56 2 [REDACTED]

10:33:59 3 [REDACTED]

10:34:02 4 [REDACTED]

10:34:03 5 [REDACTED] [REDACTED]

10:34:04 6 [REDACTED] [REDACTED]

10:34:05 7 [REDACTED] [REDACTED]

10:34:07 8 [REDACTED]

10:34:07 9 [REDACTED] [REDACTED]

10:34:10 10 [REDACTED] [REDACTED]

10:34:12 11 [REDACTED]

10:34:16 12 [REDACTED] [REDACTED]

10:34:18 13 [REDACTED]

10:34:18 14 [REDACTED] [REDACTED]

10:34:25 15 [REDACTED]

10:34:28 16 [REDACTED]

10:34:32 17 [REDACTED] [REDACTED] [REDACTED]

10:34:35 18 [REDACTED] [REDACTED]

10:34:37 19 [REDACTED]

10:34:41 20 [REDACTED]

10:34:45 21 [REDACTED]

10:34:49 22 [REDACTED]

10:34:54 23 A. I believe that's what's intended here.

10:34:56 24 Q. Okay. The model 505 and the model 750 do

10:35:07 25 not share filter characteristics; do they?

10:35:10 1 MR. BLACKWELL: I object to the form of the
10:35:11 2 question.

10:35:11 3 Q. Well in fact, let me ask --

10:35:13 4 I might need to clear that up. At the time
10:35:15 5 that both units were released and cleared to market,
10:35:19 6 those two units, the model 505 and the model 750, did
10:35:23 7 not share the same filter characteristics.

10:35:26 8 MR. BLACKWELL: Same objection.

10:35:29 9 A. Well, I mean, nor did we claim that they
10:35:32 10 would share all the same characteristics.

10:35:36 11 MR. BANKSTON: Okay. Object as non-
10:35:39 12 responsive.

10:35:39 13 Q. And I'm just trying to figure out --

10:35:41 14 I assume from that answer -- I think I know
10:35:43 15 the answer -- but those two units, the model 750 and
10:35:46 16 the model 505, they had different filter
10:35:49 17 characteristics.

10:35:51 18 A. Well of -- of course they had different.
10:35:54 19 One is -- one is a cylindrical filter, the other is a
10:35:57 20 rectangular filter. They're -- they're quite
10:36:00 21 different in -- in physical characteristics for
10:36:05 22 example, and I believe, as I'm sitting here today,
10:36:09 23 that the filter media was different in those two
10:36:12 24 filters.

10:36:12 25 Q. Okay. So we have a few different

10:36:15 1 characteristics between the two filters. Its physical
10:36:18 2 size is different.

10:36:19 3 A. Yes.

10:36:19 4 Q. Its shape is different.

10:36:21 5 A. Yes.

10:36:22 6 Q. The media used within the filter is
10:36:24 7 different.

10:36:25 8 A. I believe that's correct.

10:36:26 9 Q. Is there any other differences?

10:36:29 10 A. Again, I would have to look at an ECO to
10:36:31 11 confirm that.

10:36:32 12 Q. To confirm that they had different media?

10:36:34 13 A. Yes.

10:36:34 14 Q. Okay. So in terms of the design decisions
10:36:39 15 made at the time of clearance with respect to filter
10:36:41 16 media of these two devices, that's not something
10:36:45 17 you're prepared to talk to me about, about whether
10:36:47 18 they share or don't share those characteristics.

10:36:52 19 A. I'm sorry. Would you re -- would you repeat
10:36:55 20 that one for me?

10:36:57 21 Q. Sure. Absolutely.

10:36:58 22 When it comes to these two devices at the
10:37:00 23 time they were cleared for sale and whether or not
10:37:02 24 they have the same filter media characteristics, that
10:37:06 25 design element is not something you're prepared to

10:37:08 1 talk about today with authority.

10:37:10 2 MR. BLACKWELL: Object to the form of the
10:37:11 3 question.

10:37:13 4 A. Again, I've looked at lots of documents. I
10:37:17 5 don't recall precisely when the changes in the 505
10:37:21 6 filter media occurred, so I --

10:37:24 7 If you have an ECO, I would be happy to
10:37:27 8 confirm that, but I -- I do not recall specifically
10:37:31 9 that they were different at the time of release.

10:37:33 10 Q. Okay. Well we know --

10:37:39 11 For instance, we know that the filter media
10:37:41 12 changed on the 505.

10:37:42 13 A. Yes.

10:37:43 14 Q. Okay. And the filter media that it changed
10:37:45 15 to is the same that the 750 has always used.

10:37:49 16 A. I believe that is correct.

10:37:50 17 Q. Okay. So at some point the 505 used the
10:37:54 18 M10, the different media, but we're not sure about the
10:37:58 19 timing of when that took place; correct?

10:38:00 20 A. I am not.

10:38:00 21 Q. Okay. So if that change occurred prior to
10:38:05 22 the release and sale of the 750, then there would be a
10:38:08 23 time on the market, when the 750 was first released,
10:38:11 24 that they both had the same filter, but if that change
10:38:14 25 was made after release, then it's possible that they

10:38:16 1 had different filters at the time of release. Does
10:38:18 2 that make sense?

10:38:19 3 MR. BLACKWELL: I object to the form of the
10:38:20 4 question.

10:38:20 5 A. Well again, it's possible, but I would like
10:38:23 6 to confirm that with -- by looking at ECOs to make
10:38:27 7 absolutely certain.

10:38:27 8 Q. Correct. Okay.

10:38:28 9 So the point of looking at the ECO would be
10:38:30 10 to determine when the media change in the 505 was
10:38:33 11 made; correct?

10:38:34 12 A. Yes.

10:38:35 13 Q. Okay. Now with respect to when both units
10:38:42 14 were cleared, comparing the model 505 at the date it
10:38:47 15 was cleared and the model 750 at the date it was
10:38:50 16 cleared, they have two different media.

10:38:53 17 MR. BLACKWELL: I object to the form of the
10:38:55 18 question.

10:38:56 19 A. Again, I -- I believe that's correct. I
10:38:59 20 would have to look at an ECO or design specifications
10:39:03 21 to make absolutely certain that that's true.

10:39:05 22 Q. Okay. Well we --

10:39:08 23 You do know with authority that the M10
10:39:10 24 filter media was used in the model 505 upon its
10:39:13 25 release.

10:39:14 1 A. Initially, yes.

10:39:14 2 Q. Okay. And you know with authority that the
10:39:17 3 model 750 was released with the M20 media; correct?

10:39:20 4 A. That's correct.

10:39:22 5 Q. Okay. So it is very apparent that at the
10:39:27 6 time of the release of those two products, they had
10:39:29 7 different filter media.

10:39:30 8 MR. BLACKWELL: I object to counsel's
10:39:32 9 narrative and I object to the form of the question.

10:39:38 10 A. Apparently at release the -- the media
10:39:41 11 appeared to be different. But again, I would -- I
10:39:45 12 would want to confirm that with an ECO.

10:39:47 13 Q. Okay. What -- what detail about that would
10:39:49 14 you want to confirm?

10:39:50 15 A. That the filter medias in the two units are
10:39:53 16 different.

10:39:53 17 Q. Okay. Now as we had discussed before,
10:40:09 18 separating out to just the model 750, and we
10:40:13 19 understood that as far as we know that was the first
10:40:15 20 time that the M20 media was included in a
10:40:18 21 commercialized device made by the company.

10:40:22 22 MR. BLACKWELL: I object as asked and
10:40:23 23 answered, and misstating his testimony also.

10:40:26 24 A. I believe that's true.

10:40:27 25 Q. Okay. So I want to talk to you about that

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10:40:29 1 point, about that design decision.

10:40:34 2 [REDACTED]

10:40:37 3 [REDACTED]

10:40:40 4 [REDACTED] [REDACTED]

10:40:43 5 [REDACTED]

10:40:46 6 [REDACTED] [REDACTED]

10:40:54 7 [REDACTED]

10:40:59 8 [REDACTED]

10:41:03 9 [REDACTED]

10:41:05 10 [REDACTED] [REDACTED] [REDACTED]

10:41:12 11 [REDACTED]

10:41:12 12 [REDACTED]

10:41:15 13 [REDACTED]

10:41:16 14 [REDACTED] [REDACTED]

10:41:17 15 [REDACTED] [REDACTED] [REDACTED]

10:41:23 16 [REDACTED]

10:41:27 17 [REDACTED]

10:41:34 18 [REDACTED] [REDACTED]

10:41:36 19 [REDACTED]

10:41:38 20 [REDACTED] [REDACTED]

10:41:40 21 [REDACTED]

10:41:42 22 [REDACTED]

10:41:45 23 [REDACTED] [REDACTED]

10:41:45 24 [REDACTED] [REDACTED]

10:41:48 25 [REDACTED]

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10:41:49	1	A. [REDACTED]	
10:41:51	2	[REDACTED] [REDACTED]	
10:41:53	3	[REDACTED]	
10:41:55	4	[REDACTED] [REDACTED]	
10:41:56	5	[REDACTED] [REDACTED] [REDACTED]	
10:41:59	6	[REDACTED]	
10:42:02	7	[REDACTED]	
10:42:05	8	[REDACTED]	
10:42:08	9	[REDACTED]	
10:42:11	10	[REDACTED] [REDACTED]	
10:42:19	11	[REDACTED]	
10:42:21	12	[REDACTED]	
10:42:24	13	[REDACTED]	
10:42:27	14	[REDACTED]	
10:42:32	15	[REDACTED]	
10:42:36	16	[REDACTED]	
10:42:37	17	[REDACTED] [REDACTED] [REDACTED]	
10:42:39	18	[REDACTED]	
10:42:42	19	[REDACTED]	
10:42:44	20	[REDACTED]	
10:42:47	21	[REDACTED]	
10:42:50	22	[REDACTED]	
10:42:54	23	[REDACTED] [REDACTED]	
10:42:57	24	[REDACTED]	
10:43:03	25	[REDACTED]	

			82
10:43:06	1	[REDACTED]	
10:43:09	2	[REDACTED] [REDACTED]	
10:43:14	3	[REDACTED] [REDACTED]	
10:43:25	4	[REDACTED] [REDACTED]	
10:43:29	5	[REDACTED]	
10:43:34	6	[REDACTED]	
10:43:37	7	[REDACTED]	
10:43:40	8	[REDACTED] [REDACTED]	
10:43:43	9	[REDACTED]	
10:43:47	10	[REDACTED]	
10:43:52	11	[REDACTED]	
10:43:55	12	[REDACTED]	
10:43:57	13	[REDACTED] [REDACTED] [REDACTED]	
10:43:59	14	[REDACTED]	
10:44:02	15	[REDACTED]	
10:44:03	16	[REDACTED] [REDACTED]	
10:44:05	17	[REDACTED]	
10:44:08	18	[REDACTED] [REDACTED] [REDACTED]	
10:44:09	19	[REDACTED]	
10:44:12	20	[REDACTED]	
10:44:17	21	[REDACTED] [REDACTED]	
10:44:20	22	[REDACTED]	
10:44:23	23	[REDACTED]	
10:44:26	24	[REDACTED]	
10:44:30	25	[REDACTED]	

			83
10:44:30	1	Q. [REDACTED]	
10:44:31	2	[REDACTED]	
10:44:33	3	[REDACTED]	
10:44:36	4	[REDACTED]	
10:44:39	5	[REDACTED] [REDACTED]	
10:44:41	6	[REDACTED]	
10:44:47	7	[REDACTED]	
10:44:48	8	[REDACTED] [REDACTED]	
10:44:50	9	[REDACTED]	
10:44:53	10	[REDACTED] [REDACTED]	
10:44:54	11	[REDACTED] [REDACTED]	
10:44:57	12	[REDACTED] [REDACTED]	
10:44:59	13	[REDACTED] [REDACTED]	
10:44:59	14	[REDACTED] [REDACTED]	
10:45:00	15	[REDACTED] [REDACTED]	
10:45:02	16	[REDACTED]	
10:45:04	17	[REDACTED] [REDACTED]	
10:45:04	18	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
10:45:07	19	[REDACTED]	
10:45:09	20	[REDACTED]	
10:45:13	21	[REDACTED] [REDACTED]	
10:45:16	22	[REDACTED]	
10:45:21	23	[REDACTED]	
10:45:25	24	[REDACTED]	
10:45:29	25	[REDACTED]	

10:45:34 1 [REDACTED]

10:45:35 2 [REDACTED] [REDACTED] [REDACTED]

10:45:37 3 [REDACTED]

10:45:39 4 [REDACTED]

10:45:43 5 [REDACTED]

10:45:45 6 [REDACTED] [REDACTED] [REDACTED]

10:45:50 7 [REDACTED]

10:45:53 8 [REDACTED]

10:45:53 9 [REDACTED] [REDACTED] [REDACTED]

10:45:55 10 [REDACTED]

10:46:00 11 [REDACTED]

10:46:02 12 [REDACTED] [REDACTED] [REDACTED]

10:46:05 13 [REDACTED]

10:46:10 14 [REDACTED]

10:46:16 15 [REDACTED]

10:46:22 16 [REDACTED] [REDACTED] [REDACTED]

10:46:34 17 made to implement the M20 filter, what was done in --

10:46:43 18 internally or externally to the company to ensure that

10:46:47 19 that change in filter efficiency did not pose a risk

10:46:51 20 of airborne contamination?

10:46:52 21 A. Again, the -- the FDA quality system

10:47:02 22 requires companies to confirm or validate that any

10:47:08 23 change or any design that's made during a development

10:47:11 24 allows the device to meet its design specifications.

10:47:16 25 All -- all of those design specifications were tested

10:47:20 1 internally, to my recollection, and it met those
10:47:27 2 specifications as they existed in 2000 or 2001, 2002,
10:47:33 3 when it came on the market.

10:47:34 4 Q. Okay. What specifically within those
10:47:40 5 specifications addresses the possibility of airborne
10:47:43 6 contamination?

10:47:45 7 A. You know, without seeing the design
10:47:53 8 requirements specification document, I -- I can't
10:47:56 9 remember specifically what -- what specific
10:48:00 10 requirement was in place to allow the device to meet
10:48:05 11 that requirement.

10:48:06 12 Q. Okay. But your testimony is there is some
10:48:08 13 sort of design specification requirement intended to
10:48:13 14 make sure the device meets a standard to prevent
10:48:16 15 airborne contamination.

10:48:18 16 A. There is no standard, there's no agency
10:48:21 17 standard, there are no guidelines or guidance
10:48:24 18 documents that specify any level of filtration or
10:48:30 19 particulate loading for forced-air warming devices.

10:48:34 20 Q. Okay. So without external agency guidance
10:48:37 21 or a standard, I take it it was incumbent during the
10:48:41 22 design decision process regarding the filter for the
10:48:44 23 company itself to ensure that that change did not pose
10:48:48 24 a risk of airborne contamination; is that correct?

10:48:49 25 MR. BLACKWELL: Object to the form of the

10:48:50 1 question.

10:48:51 2 A. The filter -- the filter was selected so
10:48:59 3 that it met the design requirements that were in place
10:49:03 4 at the time that the FDA clearance occurred.

10:49:07 5 Q. Okay. But you will agree with me the
10:49:11 6 company needs to ensure that its product doesn't cause
10:49:14 7 airborne contamination.

10:49:16 8 MR. BLACKWELL: I object to the form of the
10:49:17 9 question.

10:49:21 10 A. Again, the -- the design requirements, if
10:49:26 11 that's a specif -- if that's a specific design
10:49:29 12 requirement, then the valid -- the -- the product
10:49:33 13 would be -- need to be validated to confirm or
10:49:36 14 validate that specification. I'm not -- I'm not sure
10:49:40 15 that that's one of the actual design requirements.

10:49:42 16 Q. Okay. So when I ask you about safety
10:49:45 17 validation for the filter design decisions in terms of
10:49:49 18 what was required and what was done, that's not
10:49:52 19 something you can talk about today.

10:49:53 20 MR. BLACKWELL: I object to the form of the
10:49:54 21 question, it misstates his testimony.

10:49:57 22 MR. BANKSTON: He can tell me if it does.

10:49:59 23 MR. BLACKWELL: Well he's spoken to it.

10:50:01 24 A. I'm sorry, would you repeat it again?

10:50:03 25 Q. Sure.

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10:50:03 1 With respect to the safety validation for
10:50:07 2 filter design, what requirements were -- there were
10:50:10 3 and what was actually done on the model 750, that's
10:50:13 4 not something you're prepared to talk about today.

10:50:15 5 MR. BLACKWELL: Object to the form of the
10:50:16 6 question.

10:50:17 7 A. Well I mean I -- again, I can tell you that
10:50:20 8 the -- there is a -- a control document, a design
10:50:26 9 requirement specification, and it's controlled in the
10:50:28 10 sense that it's like an ECO, that any requirement
10:50:32 11 that's on that document is approved and signed off and
10:50:35 12 it doesn't change without some sort of tracking
10:50:38 13 occurring, that all of those specifications were met
10:50:43 14 in -- in a -- or validated finally before the product
10:50:47 15 was put on the market.

10:50:48 16 [REDACTED]
10:50:51 17 [REDACTED]
10:50:54 18 [REDACTED]
10:50:55 19 [REDACTED]
10:50:59 20 [REDACTED]
10:51:02 21 [REDACTED]
10:51:05 22 [REDACTED]
10:51:08 23 [REDACTED]
10:51:12 24 [REDACTED]
10:51:15 25 [REDACTED]

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10:51:16	1	[REDACTED]	[REDACTED]
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10:51:20	3	[REDACTED]	[REDACTED]
10:51:23	4	[REDACTED]	[REDACTED]
10:51:29	5	[REDACTED]	[REDACTED]
10:51:32	6	[REDACTED]	[REDACTED]
10:51:33	7	[REDACTED]	[REDACTED]
10:51:36	8	[REDACTED]	[REDACTED]
10:51:39	9	[REDACTED]	[REDACTED]
10:51:42	10	[REDACTED]	[REDACTED]
10:51:43	11	[REDACTED]	[REDACTED]
10:51:47	12	[REDACTED]	[REDACTED]
10:51:49	13	[REDACTED]	[REDACTED]
10:51:52	14	[REDACTED]	[REDACTED]
10:51:54	15	[REDACTED]	[REDACTED]
10:51:57	16	[REDACTED]	[REDACTED]
10:51:58	17	[REDACTED]	[REDACTED]
10:52:02	18	[REDACTED]	[REDACTED]
10:52:04	19	[REDACTED]	[REDACTED]
10:52:07	20	[REDACTED]	[REDACTED]
10:52:10	21	[REDACTED]	[REDACTED]
10:52:13	22	[REDACTED]	[REDACTED]
10:52:16	23	[REDACTED]	[REDACTED]
10:52:17	24	[REDACTED]	[REDACTED]
10:52:18	25	[REDACTED]	[REDACTED]

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Q. Okay. Now part of the reason that dictated a choice of filter in the model 750 was an airflow concern; correct?

A. Part of what, yes.

Q. In fact, it was a goal of the project of the 750 to create a device which delivered more air than the previous device.

A. Yes.

Q. Okay. So the air-output specifications of the unit changed and that in turn dictated some of the choice for the filter.

A. One -- one of the many design considerations that dictated that, yes.

Q. Okay. Before the 750 was ever released and sold and used on a patient, what was done to ensure that that change in air out -- output had no adverse effect on airborne contamination issues?

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10:54:57 1 A. Well to my knowledge there were no tests
10:55:02 2 that looked at airborne particulate levels with the
10:55:05 3 new device before it went on the market.

10:55:07 4 Q. Okay. Now during the normal course of
10:55:25 5 business, the company will continuously re-evaluate
10:55:30 6 its design over the life of the unit; correct?

10:55:32 7 A. Depending on customer concerns and things of
10:55:39 8 that type, yes, we -- we re-evaluate products in a
10:55:45 9 post-market surveillance method, yes.

10:55:47 10 Q. And with respect to the Bair Hugger 500 and
10:55:52 11 700 series units, over the years there have been times
10:55:55 12 when the company, in terms of its filter design
10:55:57 13 decisions, has re-evaluated and re-explored that
10:56:02 14 issue; correct?

10:56:02 15 A. To my knowledge, the -- the -- the reason
10:56:13 16 that filter -- filter design was re-evaluated had more
10:56:18 17 to do with the vendor's inability to provide us the
10:56:22 18 current filter media.

10:56:25 19 Q. Okay. And first I want to make sure that --
10:56:30 20 I know you're -- you're kind of seeing where
10:56:32 21 I'm going, and -- and my -- my question was just:
10:56:35 22 There have been occasions over the years where the
10:56:37 23 filter issue has been re-explored or re-examined.

10:56:39 24 A. Yeah, occasionally, especially during the
10:56:44 25 design.

10:56:44 1 Q. Correct. Okay. So one of --

10:56:46 2 Let's talk about what some of those might
10:56:48 3 be. And I believe one of them you told me was that
10:56:51 4 there was some exploration and re-examination of the
10:56:53 5 filter issues when your supplier told you they could
10:56:58 6 no longer provide the filter they were providing to
10:56:58 7 you; correct?

10:56:59 8 A. Correct.

10:56:59 9 Q. Okay. Are you aware sitting here today of
10:57:02 10 other times when filter design decisions were explored
10:57:05 11 or re-evaluated by the company in any sort of special
10:57:08 12 project?

10:57:08 13 A. Well during the -- during the design phase
10:57:14 14 of the 750 several motor/blower combination designs
10:57:20 15 were evaluated which necessitated a different design
10:57:26 16 for the -- for a filter to just accommodate the size
10:57:30 17 of the whole unit.

10:57:31 18 Q. Okay. And I'm talking post clearance. When
10:57:34 19 we're talking about the products that are already on
10:57:37 20 sale for the market, do you know sitting here today
10:57:40 21 other times at which the filter issue was re-examined
10:57:42 22 or re-evaluated by the company?

10:57:44 23 A. Oh, there were -- there were some concerns
10:57:50 24 regarding the location of the louvers on the bottom of
10:57:54 25 the intake on the 750, for example, that were

10:57:57 1 redesigned to minimize the likelihood that any liquids
10:58:03 2 that happened to be on the operating room floor
10:58:05 3 wouldn't be ingested, for example.

10:58:10 4 Q. And was that problem solved?

10:58:11 5 A. Yes.

10:58:12 6 Q. Okay. You have not had -- not had
10:58:17 7 reoccurrence of fluid coming into the unit?

10:58:19 8 A. No.

10:58:20 9 Q. Okay.

10:58:20 10 A. Not to my knowledge.

10:58:23 11 Q. [REDACTED]

10:58:29 12 [REDACTED]

10:58:30 13 [REDACTED] [REDACTED]

10:58:30 14 [REDACTED] [REDACTED] [REDACTED]

10:58:33 15 [REDACTED]

10:58:37 16 [REDACTED]

10:58:37 17 [REDACTED] [REDACTED]

10:58:37 18 [REDACTED] [REDACTED] [REDACTED]

10:58:40 19 [REDACTED]

10:58:44 20 [REDACTED] [REDACTED]

10:58:53 21 [REDACTED]

10:59:01 22 [REDACTED]

10:59:01 23 [REDACTED]

10:59:07 24 [REDACTED]

10:59:10 25 [REDACTED]

10:59:13	1	[REDACTED]
10:59:14	2	[REDACTED] [REDACTED] [REDACTED]
10:59:17	3	[REDACTED] [REDACTED]
10:59:17	4	[REDACTED] [REDACTED] [REDACTED]
10:59:20	5	[REDACTED]
10:59:20	6	[REDACTED] [REDACTED]
10:59:21	7	[REDACTED] [REDACTED] [REDACTED]
10:59:22	8	[REDACTED]
10:59:23	9	[REDACTED] [REDACTED]
10:59:27	10	[REDACTED]
10:59:27	11	[REDACTED] [REDACTED]
10:59:28	12	[REDACTED] [REDACTED]
10:59:30	13	[REDACTED] [REDACTED]
11:00:00	14	[REDACTED]
11:00:03	15	[REDACTED] [REDACTED]
11:00:04	16	[REDACTED]
11:00:06	17	[REDACTED] [REDACTED]
11:00:16	18	[REDACTED]
11:00:23	19	[REDACTED]
11:00:29	20	[REDACTED]
11:00:34	21	[REDACTED]
11:00:40	22	[REDACTED]
11:00:44	23	[REDACTED]
11:00:50	24	[REDACTED] [REDACTED]
11:00:52	25	[REDACTED]

11:00:56 1 A. We certainly did enormous amounts of
11:01:00 2 literature review at -- at the time to determine
11:01:07 3 whether there was some validity to Dr. Augustine's
11:01:09 4 assertions.

11:01:11 5 Q. You can appreciate, though, that wasn't
11:01:14 6 really the question, though, I was asking though;
11:01:14 7 right?

11:01:16 8 MR. BLACKWELL: I object and move to strike
11:01:17 9 it as argumentative. If you have a question, put it
11:01:19 10 to him, but statements like these he does not respond
11:01:21 11 to.

11:01:21 12 Q. I'm just wondering if -- if my -- if my --
11:01:24 13 if my question was clear. Did you understand --

11:01:27 14 A. I thought I understood your question.

11:01:27 15 Q. Okay. Now my --

11:01:27 16 MR. BLACKWELL: And he has answered the
11:01:29 17 question.

11:01:29 18 Q. The question I had is: Did the company do
11:01:31 19 any testing to determine whether that risk was a -- it
11:01:35 20 was something of concern?

11:01:36 21 MR. BLACKWELL: I object to the question as
11:01:37 22 asked and answered.

11:01:38 23 A. The answer is yes.

11:01:40 24 Q. What testing was performed at that time?

11:01:42 25 A. There was testing done to look at

11:01:48 1 particulate loads in laminar airflow operating rooms
11:01:53 2 to determine whether the Bair Hugger warming system
11:01:58 3 increased or decreased or had no effect on particulate
11:02:02 4 loads.

11:02:02 5 Q. Is this a reference to the work by Sessler,
11:02:07 6 Olmstead and Kuelpmann?

11:02:09 7 A. Yes.

8 Q. Okay.

11:02:10 9 A. That's one example, yes.

11:02:11 10 Q. Okay. And I'd be right that that would be
11:02:13 11 sometime around the 2011 timeframe?

11:02:15 12 A. I think that was approximately when that
11:02:17 13 paper was published.

11:02:18 14 Q. [REDACTED]
11:02:21 15 [REDACTED]
11:02:26 16 [REDACTED]
11:02:28 17 [REDACTED]
11:02:33 18 [REDACTED]
11:02:35 19 [REDACTED]
11:02:37 20 [REDACTED]
11:02:40 21 [REDACTED]
11:02:42 22 [REDACTED]
11:02:42 23 [REDACTED]
11:02:44 24 [REDACTED]
11:02:50 25 [REDACTED]

11:02:53 1 be allowed to pass through the filter and it be
11:02:55 2 dangerous.

11:02:56 3 MR. BLACKWELL: I object to the form of the
11:02:57 4 question.

11:02:58 5 A. I'm not -- at -- at --

11:03:07 6 At that time? I -- I don't think we had --
11:03:09 7 we knew.

11:03:10 8 Q. Okay. Now the filtration efficiencies of
11:03:29 9 the filters that were used in Bair Hugger products,
11:03:32 10 some documentation was retained regarding their
11:03:34 11 efficiency; correct?

11:03:35 12 A. Well the -- the -- the designation of the
11:03:41 13 filter media type was certainly retained on the ECOs.

11:03:45 14 Q. Okay.

11:03:46 15 A. I'm not certain I've seen specifications
11:03:49 16 from Porous Media that indicate what the level of
11:03:54 17 efficiency was.

11:03:55 18 Q. Okay. So it would be fair to say that that
11:04:00 19 was not the kind of information -- filtration
11:04:04 20 efficiencies was not the kind of information that was
11:04:06 21 typically passed on to the customer.

11:04:09 22 A. That's correct.

11:04:10 23 MR. BANKSTON: Okay. Let's take a quick
11:04:20 24 break.

11:04:20 25 THE REPORTER: Off the record, please.

11:14:37 1 (Recess taken.)

11:14:37 2 BY MR. BANKSTON:

11:14:45 3 Q. Mr. Van Duren, we've -- we've discussed

11:14:48 4 today during some of your testimony certain documents

11:14:50 5 that are kept at 3M that you've reviewed, including

11:14:54 6 ECOs or product manufacturing specifications that

11:14:58 7 you've looked at. Those items are part of your

11:15:01 8 preparation to talk about a filter today; correct?

11:15:03 9 A. They were.

11:15:04 10 Q. Okay. Is there any reason you didn't bring

11:15:06 11 any of those documents today?

11:15:08 12 A. I -- I don't ever bring documents to a

11:15:11 13 deposition.

11:15:11 14 Q. [REDACTED]

11:15:18 15 [REDACTED]

11:15:22 16 [REDACTED]

11:15:26 17 [REDACTED]

11:15:30 18 [REDACTED]

11:15:34 19 [REDACTED] [REDACTED] [REDACTED]

11:15:39 20 [REDACTED]

11:15:47 21 [REDACTED] [REDACTED]

11:15:52 22 [REDACTED]

11:15:55 23 [REDACTED] [REDACTED]

11:15:58 24 [REDACTED]

11:16:00 25 [REDACTED].

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11:17:23 1 [REDACTED]

11:17:26 2 [REDACTED]

11:17:28 3 [REDACTED] [REDACTED]

11:17:33 4 [REDACTED]

11:17:36 5 [REDACTED]

11:17:40 6 Q. Okay. It's true that it would have been

11:17:45 7 possible to implement a HEPA filter on the device and

11:17:48 8 maintain an acceptable level of airflow.

11:17:54 9 A. I -- I don't have any engineering data to

11:17:58 10 suggest that that's true. I haven't seen any

11:18:02 11 engineering test data that would suggest that that's

11:18:06 12 true.

11:18:06 13 Q. Okay. Now after acquisition by 3M, there

11:18:16 14 have been occasions in the preceding six, seven years

11:18:21 15 in which 3M employees have re-examined and re-

11:18:26 16 evaluated the filter on the Bair Huggers; correct?

11:18:27 17 A. I'm -- I'm not sure what you mean

11:18:35 18 specifically by that.

11:18:35 19 Q. Well I'm taking that, as part of your

11:18:37 20 preparation today, that you went and made yourself

11:18:40 21 familiar with the course of design decisions and

11:18:42 22 design validations for the filter on the Bair Hugger;

11:18:44 23 correct?

11:18:44 24 A. Yes.

11:18:45 25 Q. Okay. And that would have included design

11:18:47 1 decisions being made at 3M.

11:18:53 2 A. To my knowledge, filter decisions --

11:18:58 3 I don't believe any filter change decisions

11:19:01 4 have been made at 3M.

11:19:02 5 Q. Okay. And just to reiterate an instruction

11:19:04 6 from earlier, when I'm asking you questions, I'm --

11:19:07 7 I'm not so much concerned about your knowledge as the

11:19:10 8 company's knowledge --

11:19:10 9 A. Right, I understand.

11:19:11 10 Q. -- and what you're able to say from the

11:19:13 11 company's perspective today.

11:19:14 12 And so what I want to know is: Has 3M

11:19:16 13 examined improving the filter on the Bair Hugger

11:19:20 14 units?

11:19:27 15 A. I do not believe so.

11:19:29 16 Q. Okay. Do you know who Winston Tan is?

11:19:33 17 A. Yes.

11:19:33 18 Q. Okay. He's an engineer with 3M; isn't he?

11:19:35 19 A. No.

11:19:36 20 Q. How would you describe his title?

11:19:37 21 A. Well he doesn't work at 3M.

11:19:39 22 Q. Oh, excuse me. I'm sorry. Okay. So Mr.

11:19:41 23 Tan is no longer with the company?

11:19:42 24 A. Dr. Tan has not -- no longer with 3M.

11:19:45 25 Q. Okay. Dr. Tan left quite recently then;

11:19:48 1 correct?

11:19:48 2 A. Yes.

11:19:49 3 Q. Okay. And Dr. Tan --

11:19:51 4 Was Dr. Tan an engineer, or how would you
11:19:52 5 describe his position?

11:19:54 6 A. He's a biomedical engineer.

11:19:56 7 Q. Okay. So are you familiar with any work Dr.
11:19:59 8 Tan has done with respect to the filter?

11:20:00 9 A. I believe he's -- I believe he's conducted
11:20:04 10 some work -- outside work to evaluate the efficiency
11:20:10 11 of the filters in the Bair Huggers.

11:20:11 12 Q. Okay. When you say he's done outside work,
11:20:14 13 what does that mean?

11:20:15 14 A. He hired a -- an outside firm that
11:20:18 15 specializes in that sort of work to evaluate the
11:20:22 16 efficiency of the filters.

11:20:23 17 Q. Okay. So that's something you reviewed
11:20:25 18 prior to the deposition today?

11:20:26 19 A. Yes.

11:20:27 20 Q. Okay. Do you know, then, from Dr. Tan's
11:20:33 21 work, do you know what the filtration efficiency at .2
11:20:37 22 micron is for the Bair Hugger 700 series filter?

11:20:41 23 A. I don't know specifically what the
11:20:43 24 efficiency is. I do know that the filter meets MERV
11:20:47 25 14 standards.

11:20:48 1 Q. Okay. Well you understand from Dr. Tan's
11:20:56 2 work that particles as large as one, two, three
11:21:02 3 microns can go through the Bair Hugger filter.
11:21:05 4 MR. BLACKWELL: I object to form of the
11:21:07 5 question.
11:21:08 6 A. I don't know that.
11:21:09 7 Q. Okay. Do you know who Universal Air is?
11:21:18 8 A. No.
11:21:20 9 Q. Okay. Do you know anything about --
11:21:23 10 And so I take it by that token you know
11:21:25 11 nothing about filter design explorations with
11:21:28 12 Universal Air.
11:21:31 13 A. Not by that name.
11:21:32 14 Q. Okay. Are you familiar with anybody in --
11:21:39 15 Kind of a preface: As we discussed before,
11:21:41 16 3M makes filters; right?
11:21:43 17 A. It does.
11:21:43 18 Q. And -- and so there are certain departments
11:21:46 19 within 3M where there are engineers who have
11:21:49 20 filtration expertise; correct?
11:21:50 21 A. Yes.
11:21:51 22 Q. Okay. Has the company, since acquisition,
11:21:56 23 ever used any of the 3M filtration resources to
11:22:01 24 explore design solutions for the Bair Hugger?
11:22:06 25 A. I am not aware of any filtration work done

11:22:12 1 internally within 3M on the Bair Hugger.

11:22:14 2 Q. Okay. Are you familiar with -- with the
11:22:52 3 term "tooling cost?"

11:22:53 4 A. Yes.

11:22:55 5 Q. Okay. When making design decisions about
11:22:59 6 the filter, something that needs to be taken in
11:23:01 7 consideration when changes are made is that there will
11:23:03 8 be a tooling cost; correct?

11:23:04 9 A. Yes.

11:23:05 10 Q. Okay. Can you explain what a tooling cost
11:23:07 11 is.

11:23:08 12 MR. BLACKWELL: I object to the question as
11:23:09 13 beyond the scope of the 30(b)(6), but you can answer
11:23:12 14 his question without binding 3M.

11:23:16 15 A. It's the -- it's the engineering cost that
11:23:19 16 is expended to build molds and fixtures and conduct
11:23:24 17 secondary operations on components before they're
11:23:27 18 assembled into a final system.

11:23:30 19 Q. Okay. Are you familiar with any time,
11:23:41 20 during the design decision process for filtration
11:23:45 21 decisions on the Bair Hugger, when any employees of
11:23:48 22 the company raised concerns that a reduction in
11:23:52 23 filtration efficiency could possibly have bad patient
11:23:56 24 outcomes?

11:24:01 25 A. Well sitting here today without looking at

11:24:04 1 any documents, I'm not aware or I don't recall any
11:24:08 2 employees raising those concerns.

11:24:09 3 Q. Okay. With regard to making the decision to
11:24:38 4 use a MERV 14 filter in the Bair Hugger, that level of
11:24:42 5 filtration, did the company have an understanding
11:24:46 6 about whether MERV 14 would be sufficient to filter
11:24:50 7 out all bacteria that was in the air that was entering
11:24:54 8 the unit?

11:24:55 9 A. Well MERV 14 is the -- is -- is in a class
11:25:01 10 of air filters that are specified by ASHRAE as being
11:25:07 11 bacterial exclusion filters and are acceptable for use
11:25:11 12 in healthcare facilities.

11:25:15 13 Q. Were you --

11:25:17 14 Did the company at any time ever explore
11:25:21 15 increasing to a MERV 15 filter?

11:25:25 16 A. I -- I don't know. I don't believe so, but
11:25:28 17 I don't know.

11:25:28 18 Q. Okay. When -- when Arizant was acquired by
11:25:56 19 3M, moving forward from that point, did 3M undertake
11:26:01 20 to do any independent re-evaluation of the safety
11:26:06 21 validation for the filters on Bair Hugger units?

11:26:11 22 A. Well it certainly reviewed all of the
11:26:14 23 evidence that we had amassed at that point.

11:26:20 24 Q. Okay.

11:26:21 25 A. Was that what you were asking?

11:26:22 1 Q. Sure. I think that's kind of what I'm
11:26:24 2 getting at.

11:26:25 3 In other words, 3M had a body of documents,
11:26:30 4 literature that it reviewed when it acquired the --
11:26:34 5 the company to help understand the device; correct?

11:26:37 6 A. And -- and before its acquisition as part of
11:26:40 7 its due diligence.

11:26:41 8 Q. Looked at those same kinds of things, --

11:26:43 9 A. That's --

11:26:44 10 Q. -- documents and published literature, that
11:26:46 11 sort of thing.

11:26:46 12 A. Yes.

11:26:47 13 Q. Okay. But in terms of physical internal
11:26:49 14 testing, has 3M ever done anything in terms of -- of
11:26:53 15 testing of the filter to ensure that the right filter
11:26:57 16 was being used on the Bair Hugger?

11:26:58 17 A. Well I mean the right filter is being used
11:27:02 18 on the Bair Hugger; it meets the ASHRAE requirements
11:27:05 19 for bacterial exclusion efficiency. So we have -- we
11:27:14 20 have certainly done lots of testing internally, not
11:27:17 21 just on the filter but on the system in general.

11:27:19 22 Q. Okay. When you say you -- you have done
11:27:22 23 internal testing on the filter at 3M, what kind of
11:27:24 24 testing are you talking about?

11:27:26 25 A. Not -- not the filter, the system itself.

11:27:28 1 Q. Oh, okay. Okay. So if we had to
11:27:34 2 summarize, I'm trying to -- to figure out what 3M is
11:27:37 3 relying on to conclude that the filter is appropriate
11:27:41 4 for the Bair Hugger, and I understand that there's an
11:27:43 5 ASHRAE standard, and I understand that there is some
11:27:46 6 literature out there, and possibly an examination of
11:27:49 7 3M internal documents, is there anything that I'm not
11:27:52 8 including in that list of things that they, 3M, has
11:27:55 9 done to examine the filter issue?

11:27:59 10 A. Well we -- again, we -- we are constantly
11:28:03 11 reviewing the clinical literature where comparisons
11:28:06 12 are made between the Bair Hugger warming units and
11:28:11 13 other -- other devices. I mean a recent paper
11:28:15 14 published by Kimberger and colleagues examined the
11:28:21 15 question of particulate -- bacterial contamination of
11:28:27 16 the surgical sterile field with both the model 750 and
11:28:33 17 also the Hot Dog warming unit -- with, by the way, the
11:28:37 18 M20 filter media -- and concluded that there was no
11:28:41 19 difference at all in the level of contamination in the
11:28:45 20 field between those two devices.

11:28:47 21 Q. Okay.

11:28:48 22 A. But we've also -- there are other --

11:28:51 23 You know, we continue to collect clinical
11:28:54 24 papers from the field, not all of which we fund.
11:28:59 25 These are independent examinations of the risk -- the

11:29:05 1 relative risk between one device and another.

11:29:07 2 Q. Okay. When making those filter decisions,
11:29:12 3 understanding the clinical literature as the company
11:29:16 4 does, the company today has an appreciation of the
11:29:21 5 importance of particulates discharged by a warming
11:29:24 6 unit.

11:29:24 7 MR. BLACKWELL: Object to the form of the
11:29:26 8 question.

11:29:27 9 A. Well we certainly -- we certainly appreciate
11:29:30 10 the perception of our customers with respect to the --
11:29:34 11 their concerns about that.

11:29:37 12 Q. Okay. If the model 750 did not have a
11:29:43 13 filtration efficiency that adequately mitigated
11:29:47 14 particulates in the air coming out after filtration,
11:29:50 15 that would be a concern to the company; correct?

11:29:51 16 MR. BLACKWELL: Object to the question as an
11:29:53 17 improper hypothetical.

11:29:54 18 A. Well, what would be more --

11:29:56 19 What would be concerning is if there was
11:29:58 20 a -- a -- a risk of surgical-site contamination,
11:30:03 21 bacterial contam -- contamination.

11:30:04 22 Q. Okay. So if -- if the 750 did not have a
11:30:11 23 filtration efficiency that ensured particulates were
11:30:14 24 not being ejected from the unit, does the company have
11:30:18 25 a position about whether that result, the increased

11:30:22 1 particulates into the air of the operating room,
11:30:24 2 increases, decreases, or doesn't do anything to the
11:30:26 3 risk of surgical-site infection?

11:30:28 4 MR. BLACKWELL: Object to the form of the
11:30:29 5 question, I object as beyond the scope of the 30(b)(6)
11:30:32 6 deposition notice, and I object as an improper
11:30:35 7 hypothetical.

11:30:39 8 A. I'm sorry, would you repeat the question?
11:30:41 9 I'm sorry.

11:30:41 10 Q. I'll give it my best shot.

11:30:43 11 A. Okay.

11:30:45 12 Q. If the 750 does not have adequate filtration
11:30:50 13 to prevent the ejection of particulates into the
11:30:52 14 operating room theater, does the company have a
11:30:55 15 position on whether that result would increase,
11:30:57 16 decrease, or do nothing to the risk of surgical-site
11:31:01 17 infection?

11:31:01 18 MR. BLACKWELL: I object as beyond the scope
11:31:03 19 of the Rule 30(b)(6) notice, I object as an improper
11:31:06 20 hypothetical, and I object as to the form of the
11:31:09 21 question. This is not one of the deposition topics
11:31:11 22 for which this witness was -- was designated.

11:31:15 23 Q. Let me --

11:31:16 24 Before you answer, because there's an
11:31:17 25 objection I need to deal with here, when you -- when

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11:31:20 1 you -- when you prepared for this deposition, one of
11:31:22 2 the topics that you prepared for was decisions
11:31:25 3 relating to the filter design, filter mediums, and
11:31:28 4 filter efficiency; correct?

11:31:29 5 A. Yes.

11:31:30 6 Q. Part of the decision-making process on
11:31:34 7 filter designs, filter medias, concerned the ability
11:31:40 8 to filter airborne particulates; correct?

11:31:43 9 A. Yes.

11:31:43 10 Q. So when filter designs were being made,
11:31:47 11 those decisions made by the company had to be made
11:31:50 12 with an understanding of the clinical significance of
11:31:54 13 airborne particulates, such that that might exist;
11:31:57 14 correct?

11:31:57 15 A. Well, during the design phase?

11:32:02 16 Q. Sure.

11:32:02 17 A. Again, I think we -- the --

11:32:07 18 The design specifications relied upon the
11:32:10 19 clinical evidence that existed at the time, which
11:32:14 20 suggests that there wasn't any increased risk from
11:32:17 21 using the level of filtration that existed all the way
11:32:21 22 from the beginning of the company.

11:32:22 23 Q. Okay. Today, from where the company sits
11:32:27 24 with the knowledge it has today, the company
11:32:32 25 understands when making filter decisions that it is

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11:32:33 1 undesirable to have particulates over the surgical
11:32:36 2 site.

11:32:36 3 A. Well it's -- it's completely impossible to
11:32:39 4 prevent particulates over the surgical site whether or
11:32:44 5 not a forced-air warming unit is in place. But our --
11:32:47 6 our reliance is on the ASHRAE specification for a MERV
11:32:52 7 14, which is designated as a filtration efficiency
11:32:57 8 adequate to prevent bacterial contamination.

11:33:00 9 Q. Okay. The company, all things being equal,
11:33:04 10 would like to take every reasonable step to mitigate
11:33:08 11 as much as possible the protect -- the emission of
11:33:11 12 particulates from the Bair Hugger.

11:33:13 13 MR. BLACKWELL: I object to the question as
11:33:15 14 asked and -- and answered, but also beyond the scope
11:33:18 15 of the Rule 30(b)(6) notice.

11:33:20 16 A. I believe the answer to that question is
11:33:22 17 that we recognize that the ASHRAE standard for bac --
11:33:26 18 bacterial elimination is met by the requirements -- or
11:33:32 19 the -- the MERV 14 specification.

11:33:35 20 Q. Okay. In other words, the reason that you
11:33:37 21 would want to follow this specification or meet this
11:33:40 22 ASHRAE standard is because you would want to take
11:33:44 23 every reasonable step to adequately mitigate the --
11:33:47 24 the ejection of particulates from the unit.

11:33:53 25 A. Well I --

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11:33:54 1 That's one reason that we would select the
11:33:56 2 filter media that we had selected, yes.

11:33:58 3 Q. Okay.

11:34:05 4 MR. BANKSTON: All right. Let's take a
11:34:07 5 little break because I think we're done with those.

11:34:09 6 THE REPORTER: Off the record, please.

12:32:18 7 (Recess taken.)

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12:32:18 1 AFTERNOON SESSION

12:32:20 2 BY MR. ASSAAD:

12:32:32 3 Q. Mr. Van Duren, again my name is Gabriel

12:32:35 4 Assaad and we've met numerous times --

12:32:36 5 A. Yes.

12:32:36 6 Q. -- and been through numerous depositions

12:32:40 7 together. I'm going to cover topics number five, six

12:32:43 8 and seven regarding the 30(b)(6) deposition notice

12:32:47 9 that you said you reviewed previously. And just to go

12:32:50 10 over the topics, number five states justification for

12:32:53 11 design changes between Bair Hugger model 700 series

12:32:56 12 and 500 series products allegedly used in plaintiffs'

12:32:59 13 surgeries at issue in this litigation. Did I read

12:33:02 14 that correctly?

12:33:03 15 A. Yes.

12:33:03 16 Q. Are you prepared to testify on behalf of 3M

12:33:07 17 regarding that subject matter number five?

12:33:08 18 A. Yes.

12:33:09 19 Q. Okay. Number six states any internal

12:33:12 20 testing performed by defendants to evaluate the

12:33:15 21 potential for the Bair Hugger patient warming system,

12:33:17 22 or any component thereof, to disrupt the sterile

12:33:20 23 surgical field, disperse airborne particles and/or

12:33:25 24 pathogens, harbor bacteria inside the device, and/or

12:33:29 25 cause surgical-site infections. Did I read that

12:33:31 1 correctly?

12:33:32 2 A. Yes.

12:33:32 3 Q. Are you prepared to testify regarding that
12:33:33 4 subject matter today on behalf of 3M?

12:33:36 5 A. Yes.

12:33:36 6 Q. Topic number seven states defendants'
12:33:39 7 knowledge and analysis of third-party testing
12:33:41 8 regarding the potential of the Bair Hugger patient
12:33:44 9 warming system, or any component thereof, to disrupt
12:33:47 10 the sterile surgical field, disperse airborne
12:33:51 11 particles and/or pathogens, harbor bacteria inside the
12 12 device, and/or cause surgical-site infect --
12:33:53 13 infection. Did I read that correctly?

12:33:54 14 A. Yes.

12:33:54 15 Q. Are you prepared to testify on behalf of 3M
12:33:58 16 regarding subject area number seven today?

12:34:00 17 A. Yes.

12:34:01 18 Q. With respect to those three subject areas,
12:34:02 19 what did you do to prepare for your corporate-
12:34:06 20 designation deposition today?

12:34:08 21 MR. BLACKWELL: I will object as asked
12:34:10 22 and -- and answered, but go ahead.

12:34:13 23 A. I reviewed testimony, I reviewed internal
12:34:17 24 documents, e-mails, clinical literature, scientific
12:34:23 25 literature, internal testing documents.

12:34:28 1 Q. And do you feel, based on your preparation
12:34:33 2 for today's deposition regarding those subject areas,
12:34:37 3 that you're -- you're the most qualified to testify
12:34:39 4 regarding those three subject areas?

12:34:41 5 A. I believe so.

12:34:43 6 Q. And you said the deposition testimony you've
12:34:45 7 read was Reed and McGovern; is that correct?

12:34:48 8 A. I -- I'm sorry?

12:34:48 9 Q. Reed and McGovern were the only two
12:34:53 10 deposition transcripts you read in preparation of
12:34:57 11 today's deposition?

12:34:57 12 A. Yes.

12:34:57 13 Q. Okay. Any other deposition testimony that
12:34:58 14 you've read?

12:34:59 15 A. I've read many depositions prior to this
12:35:00 16 date, but not in preparation for this deposition.

12:35:02 17 Q. Now with respect to the internal documents
12:35:16 18 and e-mails, do you feel that you're prepared today to
12:35:26 19 refer to them specifically in the answering of these
12:35:29 20 questions?

12:35:29 21 MR. BLACKWELL: I'll object to form of the
12:35:30 22 question.

12:35:33 23 A. If you present them to me, I will ans --
12:35:35 24 yeah, I will respond to the questions, yes.

12:35:36 25 Q. Well it's very hard for me to present them

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12:35:39 1 to you since I don't know what you reviewed. So are
12:35:42 2 you prepared to specifically identify the -- the
12:35:44 3 documents that you are relying upon in answering these
12:35:48 4 questions today?

12:35:48 5 A. No.

12:35:48 6 MR. BLACKWELL: Object to the form of the
12:35:49 7 question.

12:35:50 8 Q. You mentioned previously that you don't
12:35:54 9 bring deposi -- you don't bring documents to
12:35:57 10 depositions. Do you recall that testimony?

12:35:58 11 A. I do.

12:35:58 12 Q. Why don't you bring documents to
12:36:01 13 depositions?

12:36:01 14 MR. BLACKWELL: Object to the question as
12:36:02 15 beyond the scope of the 30(b)(6) notice.

12:36:08 16 A. It's just unnecessary to --

12:36:09 17 You don't bring loose change to combat.

12:36:12 18 Q. Do you think those documents would help you
12:36:15 19 answer these questions and would be able when you --
12:36:17 20 so you had the opportunity to refer to them in
12:36:18 21 answering the questions today on behalf of 3M?

12:36:21 22 MR. BLACKWELL: Object to the question as
12:36:22 23 calling for speculation.

12:36:23 24 A. They might, but I have no idea what
12:36:26 25 documents you're going to ask me questions about.

12:36:28 1 Q. I understand that. But you referred --

12:36:29 2 You reviewed many documents in preparation
12:36:31 3 of the subject matter today; correct?

12:36:34 4 A. I did.

12:36:35 5 Q. And you used those documents to prepare you
12:36:37 6 to help answer the questions that you may be rec --
12:36:38 7 that we may be asking today in this deposition;
12:36:41 8 correct?

12:36:41 9 A. Yes.

12:36:41 10 Q. And I think you referred to many documents
12:36:44 11 that you reviewed in answering questions earlier;
12:36:47 12 correct?

12:36:47 13 A. Yes.

12:36:47 14 Q. And many of the times you said "I don't
12:36:50 15 remember. I don't recall the document." Do you
12:36:52 16 remember that testimony?

12:36:52 17 A. Yes.

12:36:53 18 Q. Do you believe if you had those documents
12:36:54 19 today, that you could refer to them and answer these
12:36:57 20 questions more specifically and more accurately?

12:36:59 21 MR. BLACKWELL: I object to the form of the
12:37:00 22 question.

12:37:00 23 A. It's -- it's possible.

12:37:02 24 Q. You don't think, if you had documents in
12:37:04 25 front of you that you reviewed, that you might not be

12:37:07 1 able to refer to them and answer questions more

12:37:10 2 accurately?

12:37:10 3 MR. BLACKWELL: Object as asked and

12:37:10 4 answered.

12:37:10 5 A. I've reviewed thousands of documents.

12:37:13 6 There's simply no way I could bring all of those or

12:37:16 7 anticipate which ones in particular you would ask

12:37:18 8 questions about.

12:37:18 9 Q. Well you know the subject matters here;

12:37:20 10 correct?

12:37:20 11 A. Yes.

12:37:21 12 Q. And one of them is justification for dine --

12:37:24 13 design changes between the Bair Hugger models;

12:37:26 14 correct?

12:37:26 15 A. Yes.

12:37:26 16 Q. One is internal testing; correct?

12:37:29 17 A. Yes.

12:37:30 18 Q. And one is third-party testing; correct?

12:37:34 19 A. Yes.

12:37:34 20 Q. So you kind of had an idea of the questions

12:37:36 21 we'll be asking you about today; correct?

12:37:37 22 MR. BLACKWELL: I object to the question --

12:37:38 23 form of the question as calling for speculation.

12:37:40 24 A. I have a --

12:37:41 25 I understand the general subject of the

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12:37:42 1 questions you're going to be asking.

12:37:47 2 Q. Now my understanding with respect to the 500
12:37:50 3 and 700 series models, there is -- let's start with
12:37:53 4 the 500 series -- is the 500, the 500 OR, the 502 and
12:37:58 5 the 505; is that correct?

12:37:59 6 A. Yes.

12:37:59 7 Q. And with the seven series -- 700 series it's
12:38:02 8 the 750 and the 775; correct?

12:38:04 9 A. Yes.

12:38:04 10 Q. Okay. Are there any other models that I
12:38:08 11 have not mentioned with respect to the 500 series and
12:38:10 12 the 700 series?

12:38:12 13 A. Well there are European versions of those
12:38:14 14 models.

12:38:14 15 Q. There's the 500E. You are correct. Is that
12:38:19 16 correct?

12:38:19 17 A. Uh-huh.

12:38:20 18 Q. Is that a yes?

12:38:21 19 A. Yes, that's a yes.

12:38:22 20 Q. And is there a 775 or 750E?

12:38:24 21 A. No.

12:38:25 22 Q. Okay.

12:38:27 23 A. But there is a 505E as well.

12:38:31 24 Q. Okay. There's a 500E and a 505E?

12:38:34 25 A. Yes.

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12:38:35 1 Q. Now is the progression, just so we stay in
12:38:46 2 order, you know, with respect to design changes, was
12:38:48 3 it the 500, the 500 OR, the 502, then the 505?

12:38:53 4 A. I believe that's the correct order.

12:38:54 5 Q. Okay. Now before we talk -- discuss about
12:39:02 6 the design changes, I'm going to start off with the
12:39:04 7 500, to get the specifications for the 500. Is that
12:39:07 8 fair? Is that a good place to start?

12:39:09 9 A. Yes.

12:39:09 10 Q. Okay. With respect to the 500, describe the
12:39:14 11 500 model with respect to its specs.

12:39:18 12 MR. BLACKWELL: Object to the form of the
12:39:19 13 question.

12:39:20 14 A. Well its exact specifications I'm not
12:39:24 15 certain of, but the -- it was the -- it was one of the
12:39:26 16 first smaller warming units that Augustine Medical
12:39:33 17 devised to enter the operating room, so its operating
12:39:38 18 temperature -- its highest operating temperature was
12:39:41 19 reduced from approximately 46 Celsius to 43 Celsius.

12:39:46 20 Q. Was the 500 --

12:39:48 21 Was the model 500 the first device that was
12:39:54 22 cleared to be used in the operating room?

12:39:55 23 A. No.

12:39:56 24 Q. What was the first device?

12:39:57 25 A. Model 250 and the model 275 and model 275E.

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12:40:10 1 Q. Just for a little bit of background, was
12:40:15 2 the maximum temperature for the 250 and the 275E 43
12:40:19 3 degrees Celsius?

12:40:20 4 MR. BLACKWELL: Object to the question as
12:40:21 5 beyond the scope of this 30(b)(6) notice.

12:40:23 6 A. Yes, it was.

12:40:24 7 Q. And what was the airflow for the model 500?

12:40:31 8 A. I don't know specifically what the airflow
12:40:33 9 is.

12:40:33 10 Q. Was it around 30 cfm?

12:40:36 11 MR. BLACKWELL: Object to the form of the
12:40:37 12 question, asked and answered.

12:40:37 13 A. I suspect it's approximately that value.

12:40:44 14 Q. Do you recall the weight of the model 500?

12:40:50 15 A. The --

12:40:51 16 Q. The weight.

12:40:51 17 A. No, I do not.

12:40:52 18 Q. Would it be around 40 to 50 pounds?

12:40:55 19 A. I don't recall. But it's on wheels. It's
12:40:57 20 not really intended to be picked up. It's on wheels.

12:41:00 21 Q. So would you agree with me that it was a
12:41:03 22 heavier device than the 505?

12:41:05 23 A. Much heavier.

12:41:07 24 Q. Did all the 500 series use the same blanket?

12:41:20 25 MR. BLACKWELL: I object to the form of the

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12:41:21 1 question as beyond the scope of this 30(b)(6) notice.

12:41:25 2 A. All of the -- all of the blankets would

12:41:27 3 attach to all of -- any of the model -- or the 500

12:41:31 4 series warming units.

12:41:32 5 Q. And the 700 series?

12:41:34 6 MR. BLACKWELL: Same objection, beyond the

12:41:36 7 scope of the 30(b)(6) notice.

12:41:37 8 A. Yes.

12:41:41 9 Q. So I take it the next model after the 500

12:41:49 10 was the 500 OR; correct?

12:41:50 11 A. Yes.

12:41:51 12 Q. What was the design change between the 500

12:41:54 13 and the 500 OR?

12:41:55 14 A. I believe that had roughly the same

12:42:04 15 operating specifications, but it was a different

12:42:06 16 physical layout of the warming unit.

12:42:10 17 Q. You mentioned "OR" was for Operating Room;

12:42:14 18 correct?

12:42:14 19 A. Yes.

12:42:15 20 Q. Okay. Why -- why did you --

12:42:17 21 What was the justification between the 500

12:42:20 22 to the 500 OR with respect to design changes to add

12:42:23 23 that OR designation?

12:42:27 24 A. Physical changes were made to the industrial

12:42:31 25 design of the device, but the operating specifications

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12:42:34 1 were essentially the same for all of the 500 series
12:42:38 2 warming units.

12:42:41 3 Q. So just so I understand, are you -- is 3M
12:42:44 4 saying that the -- the specifi -- specification with
12:42:50 5 respect to air output and temperature are the same
12:42:52 6 between all the 500 series?

12:42:53 7 A. They're not identical, but they're roughly
12:42:56 8 equivalent --

12:42:57 9 Q. Okay.

12:42:57 10 A. -- or substantially equivalent.

12:42:59 11 Q. What -- what was the physical changes
12:43:00 12 between the 500 and the 500 OR?

12:43:03 13 A. The size is different, the motor is a
12:43:11 14 different motor/blower combination, the controller is
12:43:17 15 a different controller, the electronic controller is
12:43:21 16 made by a different company, I believe the heater is a
12:43:23 17 different heater. So a lot of the internal components
12:43:28 18 changed, a lot of the industrial design changed.

12:43:35 19 Q. Okay. By giving the OR designation to that
12:43:42 20 500 model, 3M is not saying that the 500 -- the plain
12:43:47 21 500 model was not supposed to be used in the OR;
12:43:50 22 correct?

12:43:50 23 MR. BLACKWELL: Object to the form of the
12:43:51 24 question.

12:43:51 25 A. That's correct.

12:43:52 1 Q. Okay. So the justification for the design
12:44:11 2 changes between the 500 and the 500 OR was basically
12:44:14 3 to make the device more compact.

12:44:19 4 A. That was one of the design goals.

12:44:23 5 Q. And what was the other goal?

12:44:24 6 A. To change the industrial design, make it
12:44:28 7 more modern, to give it some added ability to move.
12:44:35 8 It had a -- it had a movable handle on it that allowed
12:44:39 9 people to move it easier.

12:44:46 10 Q. The next 500 series that came was the 502;
12:44:52 11 correct?

12:44:52 12 A. I believe that's correct, yes.

12:44:53 13 Q. What's the difference between the 502 and
12:44:56 14 the 500 OR?

12:44:57 15 A. Again, there were some component changes,
12:45:00 16 internal component changes, industrial design changes.

12:45:05 17 Q. Did it have pretty much the same specs with
12:45:08 18 respect to temperature and output?

12:45:09 19 A. The same specifications with respect to
12:45:15 20 temperature. I believe the airflow was different.

12:45:17 21 Q. And what was the difference in airflow?

12:45:19 22 A. I believe it was greater in the 500. I'm
12:45:23 23 not certain.

12:45:24 24 Q. Okay. Was the 502 ever placed into market?

12:45:44 25 A. I'm not sure what you mean.

12:45:46 1 Q. Well was it ever placed or in -- in
12:45:49 2 hospitals or healthcare providers? Like was it ever
12:45:51 3 marketed, was it ever commercialized?

12:45:53 4 MR. BLACKWELL: I object to the question as
12:45:54 5 beyond the scope of the 30(b)(6) notice.

12:45:56 6 Q. Well I just want to know if I need to ask
12:46:00 7 any more questions. If it just was a model number
12:46:02 8 then that they never marketed, I'm just trying to get
12:46:05 9 this straight.

12:46:05 10 A. It was placed in healthcare facilities.

12:46:07 11 Q. Okay. What was the justification with the
12:46:16 12 502 to have less airflow than the 500?

12:46:20 13 A. The performance of the warming system within
12:46:29 14 a given range is roughly the same regardless of what
12:46:33 15 the airflow is in -- when it's unrestrained. So once
12:46:39 16 a blanket is attached to a warming unit, the airflow
12:46:43 17 is substantially reduced, and within relatively large
12:46:50 18 ranges the overall performance is not substantially
12:46:55 19 affected.

12:46:58 20 Q. So if I understand you correctly, when --
12:47:00 21 when the blanket is -- is put on, the airflow is
12:47:03 22 substantially reduced and therefore the -- the
12:47:07 23 differences in -- the minor differences in airflow
12:47:11 24 between the 500 and the 502 is insignificant.

12:47:15 25 A. The -- that's --

12:47:19 1 That's roughly correct, yes.

12:47:21 2 Q. So my statement's correct?

12:47:22 3 A. I'm sorry?

12:47:23 4 Q. My statement is correct?

12:47:24 5 A. It is.

12:47:25 6 Q. Okay. When you used the term

12:47:41 7 "substantially reduced," what do you mean by

12:47:43 8 "substantially reduced?"

12:47:45 9 A. Maybe re -- reduced from an airflow in free

12:47:53 10 air, reduced to a value that's, say, a third of that

12:47:58 11 value, whatever it is. And it depends on the blanket

12:48:05 12 type; different blankets reduce airflow by different

12:48:08 13 amounts.

12:48:08 14 Q. And that -- that depends on the back-

12:48:11 15 pressure.

12:48:11 16 A. Yeah. The resistance of the blanket,

12:48:14 17 correct.

12:48:15 18 Q. The 505 was -- was the next and final model

12:48:40 19 in this -- in the 500 series; correct?

12:48:42 20 A. That's right.

12:48:43 21 Q. Okay. And what was the design changes

12:48:45 22 between the 500 -- 505 and the 502?

12:48:48 23 A. They were substantial. The -- the entire

12:48:52 24 system was redesigned to make it possible to mount it

12:48:58 25 on an IV pole. It didn't have wheels. The control

12:49:03 1 system I believe is -- was a entirely new control
12:49:07 2 scheme. Heater was different, motor is different.
12:49:12 3 Everything was made to make it lighter, smaller,
12:49:15 4 quieter.

12:49:19 5 Q. In what year did the 505 come out?

12:49:24 6 A. 1996 I believe is the year it came out.

12:49:30 7 Q. And with respect to the specifications of
12:49:37 8 heat output and -- and airflow, were they
12:49:40 9 substantially similar to the 502?

12:49:43 10 A. They were substantially equivalent to that
12:49:46 11 value.

12:49:47 12 Q. Okay. And would it be fair that the -- on
12:49:51 13 the specifications for the 505, the airflow was 30
12:49:56 14 cfm?

12:49:56 15 A. It's somewhere in that range in free air,
12:49:59 16 yes.

12:49:59 17 Q. When you say "free air," that's when it's
12:50:01 18 not attached to a blanket; correct?

12:50:03 19 A. Anything. Correct.

12:50:04 20 Q. Okay. Well besides a blanket, is there
12:50:08 21 anything else it could be attached to?

12:50:09 22 A. Temperature test kit.

12:50:10 23 Q. Okay.

12:50:11 24 A. We have -- we have phantoms that can be
12:50:13 25 placed in the -- at the end of the hose to do

12:50:16 1 calibration work.

12:50:17 2 Q. Well besides calibration work, I mean the --
12:50:21 3 the only other -- the thing that it would be attached
12:50:23 4 to would be another -- to a blanket; correct?

12:50:25 5 A. Or a gown, yes.

12:50:27 6 Q. And was the temperature -- the maximum
12:50:34 7 temperature also 43 degrees Celsius?

12:50:36 8 A. Yes.

12:50:36 9 Q. And with respect to -- and this is going to
12:50:39 10 lead up to my 700 series questions -- but with respect
12:50:41 11 to the temperature measurement, the temperature
12:50:44 12 measurement was done at the output of the actual
12:50:52 13 casing of the 500 series; correct?

12:50:55 14 A. The temperature was measured internally to
12:50:58 15 the warming system, correct.

12:50:59 16 Q. And that was after the heating coil.

12:51:01 17 A. Yes.

12:51:02 18 Q. Okay. Right before the air was exhausted
12:51:05 19 into the hose.

12:51:06 20 A. Yes.

12:51:07 21 Q. And just to speed up things, one of the
12:51:12 22 design changes from the 500 series to the 700 series
12:51:15 23 is that temperature measurement in the 700 series was
12:51:18 24 taken at the end of the hose before it went into the
12:51:20 25 blanket; correct?

12:51:21 1 A. That is correct.

12:51:22 2 Q. There was a thermocouple entered -- placed
12:51:25 3 at the end of the hose.

12:51:26 4 A. It's not a thermocouple. It's a
12:51:29 5 semiconductor temperature sensor, two of them
12:51:31 6 actually.

12:51:32 7 Q. And that was one of the major design changes
12:51:42 8 between the 700 series and the 500 series; correct?

12:51:44 9 A. One of.

12:51:45 10 Q. Yeah, one of. I didn't say the only one,
12:51:48 11 but one of.

12:51:49 12 A. Yeah. No. One of.

12:51:50 13 Q. What other design changes are there between
12:51:52 14 the 500 series and the 700 series?

12:51:54 15 A. There are a number of them. One of the
12:51:57 16 major changes that we made was in the con -- in the
12:52:02 17 control scheme. We went from a -- a single-element
12:52:06 18 heater in the 500 series to a three-element heater in
12:52:11 19 the 700 series, and that was done primarily to limit
12:52:16 20 the amount of loading -- line loading that we got so
12:52:20 21 that it -- you could prevent the lights from
12:52:23 22 flickering in the operating room.

12:52:25 23

12:52:28 24

12:52:31 25

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			130
12:52:34	1	[REDACTED]	
12:52:36	2	[REDACTED]	
12:52:39	3	[REDACTED] [REDACTED]	
12:52:43	4	[REDACTED]	
12:52:45	5	[REDACTED]	
12:52:46	6	[REDACTED] [REDACTED]	
12:52:50	7	[REDACTED]	
12:52:53	8	[REDACTED]	
12:52:56	9	[REDACTED] [REDACTED]	
12:53:00	10	[REDACTED]	
12:53:03	11	[REDACTED]	
12:53:06	12	[REDACTED]	
12:53:08	13	[REDACTED]	
12:53:11	14	[REDACTED]	
12:53:13	15	[REDACTED] [REDACTED]	
12:53:14	16	[REDACTED] [REDACTED]	
12:53:17	17	[REDACTED]	
12:53:20	18	[REDACTED]	
12:53:24	19	[REDACTED]	
12:53:27	20	[REDACTED] [REDACTED] [REDACTED]	
12:53:34	21	[REDACTED]	
12:53:34	22	[REDACTED] [REDACTED]	
12:53:35	23	[REDACTED] [REDACTED]	
12:53:37	24	[REDACTED] [REDACTED]	
12:53:39	25	[REDACTED]	

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12:53:41 1 [REDACTED]

12:53:43 2 [REDACTED]

12:53:52 3 [REDACTED]

12:53:54 4 [REDACTED]

12:53:57 5 [REDACTED]

12:53:59 6 [REDACTED]

12:54:03 7 Q. Any other major changes? Or major or minor.

12:54:08 8 A. Well the -- the motor was changed from a

12:54:14 9 standard induction motor to a -- to an electrically

12:54:18 10 commutated motor which allowed us to control its speed

12:54:21 11 more precisely. Also, it made it possible to make

12:54:28 12 models for different main voltages in Europe and

12:54:32 13 elsewhere without having to change the motor for

12:54:36 14 different voltages and line frequencies. The heater

12:54:40 15 obviously was changed, it's a three-element, one-

12:54:43 16 kilowatt heater as opposed to a single-element heater,

12:54:47 17 but the -- the overall total power displacement of the

12:54:51 18 heater is about a kilowatt.

12:54:53 19 Q. What about with airflow, any changes in the

12:54:56 20 airflow?

12:54:57 21 A. Yeah. The airflow was increased somewhat

12:54:59 22 substantially.

12:55:00 23 Q. What was the justification for increasing

12:55:02 24 the airflow?

12:55:03 25 A. Better performance, better heat-transfer

12:55:07 1 performance.

12:55:09 2 Q. You said "better heat-transfer performance."

12:55:11 3 What do you mean by that?

12:55:12 4 A. That the amount of heat transferred to the

12:55:14 5 patient would be greater with the model 700 series.

12:55:21 6 Q. Now to avoid many questions, is the only

12:55:28 7 difference between the 750 and the 775 is that the 775

12:55:33 8 has a variable motor, so it has two speeds?

12:55:38 9 A. That -- that's the only significant change

12:55:40 10 between the two.

12:55:41 11 Q. Okay. The 775 could run at 30 cfm or 48

12:55:47 12 cfm; correct?

12:55:47 13 A. Yes.

12:55:48 14 Q. 750 only runs at 48 cfm; correct?

12:55:51 15 A. In free air, right. No resistance.

12:55:53 16 Q. So let's assume when I'm -- when I'm ticking

12:55:56 17 the specs off we're talking free air; correct?

12:55:58 18 A. Yes.

12:55:58 19 Q. Because depending on the blanket, for

12:56:00 20 example like a 522, the cfm is about 42 to 45;

12:56:05 21 correct?

12:56:05 22 A. I -- I believe it's in that range.

12:56:07 23 Q. Okay. And that's because of the resistance

12:56:10 24 of the blanket; correct?

12:56:11 25 A. Yes.

12:56:11 1 Q. Okay. Did -- did increasing the airflow
12:56:15 2 have any advantage with respect to the resistance?

12:56:21 3 Withdraw the question.

12:56:21 4 Before we get there, you said you could
12:56:23 5 control the motor more accurately in the 750 because
12:56:28 6 of the controls and the motor type that was used;
12:56:31 7 correct?

12:56:31 8 A. Yes.

12:56:32 9 Q. Is the -- is the motor a single-speed motor
12:56:35 10 or is it a variable motor that could increase based on
12:56:39 11 the resistance of the blanket?

12:56:40 12 A. Well the motor itself is a variable-speed
12:56:43 13 motor, but it's operated at a single, fixed speed by
12:56:45 14 the controller. It doesn't change its speed.

12:56:47 15 Q. Okay. So whether or not --

12:56:49 16 It doesn't take into account the resistance
12:56:51 17 based on the -- the end of the ho -- what's at the end
12:56:54 18 of the hose.

12:56:55 19 A. The controller tries to maintain the motor
12:56:57 20 speed regardless of the external resistance presented
12:57:01 21 to it.

12:57:01 22 Q. Okay.

12:57:02 23 A. So that's another advantage, that the --
12:57:05 24 the -- the 700 series was able to detect, if the motor
12:57:12 25 stopped operating for any reason, so if -- if the

12:57:16 1 motor seized, for example, during operation, the
12:57:20 2 controller would shut the heater down and -- and give
12:57:22 3 an alarm condition. So that's something that we
12:57:24 4 couldn't have done in the model 500 series because
12:57:28 5 those -- that technology hadn't been developed at that
12:57:31 6 point.

12:57:35 7 Q. You said the higher air output of the 700
12:57:41 8 series increased performance and heat transfer, and
12:57:45 9 that's one of the justifications for the design
12:57:47 10 change; correct?

12:57:48 11 A. Yes.

12:57:48 12 Q. Okay. What -- what --

12:57:52 13 How did it increase heat transfer?

12:57:55 14 A. So in a --

12:57:58 15 For forced-air warming, there are two things
12:58:01 16 that really affect heat transfer into the patient:
12:58:06 17 one is the airflow that is coming from the blanket;
12:58:09 18 and the other is the temperature difference between
12:58:12 19 the patient's skin and the air impinging on it.

12:58:15 20 Q. The delta.

12:58:15 21 A. Yes, correct.

12:58:17 22 Q. The delta T between the forced-air warming
12:58:20 23 blanket and the skin of the patient?

12:58:23 24 A. Yes.

12:58:23 25 Q. Okay.

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12:58:23 1 A. So unlike conductive and radiative devices
12:58:26 2 where you really only have -- you can only control
12:58:29 3 the -- the -- the T infinity or the -- the temperature
12:58:33 4 of the device, with forced-air warming you can control
12:58:36 5 both the airflow h or the delta T, and both of those
12:58:41 6 have an influence on the heat transfer into the
12:58:44 7 patient.

12:58:49 8 Q. Well isn't the delta T a constant?

12:58:52 9 A. No, it's not.

12:58:53 10 Q. I mean if -- if you put it to the highest
12:58:56 11 level of 42 degrees, isn't it a constant?

12:58:59 12 A. Well the delta is not constant. The -- the
12:59:01 13 impinging temperature is fixed, yes.

12:59:04 14 Q. What do you mean by "the impinging?" That's
12:59:06 15 the temperature coming out of the blanket?

12:59:07 16 A. The air temperature impinging the skin of
12:59:10 17 the patient. But the delta doesn't remain constant
12:59:12 18 because the patient's skin temperature increases.

12:59:25 19 Q. Was there any testing with respect to the
12:59:27 20 heat-transfer rates and the differen -- and the
12:59:30 21 differences between the 500 series and the 700 series?

12:59:34 22 A. Yes.

12:59:35 23 Q. Internal testing or --

12:59:36 24 A. Yes.

12:59:36 25 Q. -- or -- let me finish -- internal or

12:59:39 1 external or both?

12:59:40 2 A. Internal only.

12:59:41 3 Q. Okay. And who did the testing?

12:59:42 4 A. A number of engineers in the Research and
12:59:46 5 Development group.

12:59:46 6 Q. [REDACTED]

12:59:48 7 [REDACTED]

12:59:52 8 [REDACTED]

12:59:56 9 [REDACTED]

13:00:01 10 [REDACTED]

13:00:05 11 [REDACTED]

13:00:07 12 [REDACTED]

13:00:10 13 [REDACTED]

13:00:13 14 [REDACTED]

13:00:17 15 [REDACTED].

13:00:21 16 Q. You used the term "convective." What do you
13:00:34 17 mean by "convective?"

13:00:35 18 A. It's a mode of heat transfer that requires a
13:00:38 19 fluid to transfer the energy from one source to
13:00:46 20 another, from a source to a target.

13:00:47 21 Q. Okay. And you also mentioned "conductive,"
13:00:51 22 and that is --

13:00:52 23 A. That's the transfer of energy by direct
13:00:55 24 contact between two surfaces of a different
13:00:58 25 temperature.

13:00:59 1 Q. You'd agree with me that the Bair Hugger
13:01:01 2 does transfer some energy by direct contact; correct?
13:01:03 3 A. Very little.
13:01:04 4 Q. But it does transfer by direct contact.
13:01:07 5 Yes?
13:01:07 6 A. Yes.
13:01:07 7 Q. Okay. So the Bair Hugger has some
13:01:11 8 convective -- conductive element to it besides the
13:01:14 9 convective element; correct?
13:01:16 10 MR. BLACKWELL: Object to the form of the
13:01:17 11 question.
13:01:17 12 A. Yes.
13:01:18 13 Q. The Bair Hugger does transfer --
13:01:20 14 There is a delta T between the -- the
13:01:23 15 outside of the blanket and the patient; correct?
13:01:25 16 A. Oh, yes.
13:01:26 17 Q. And when that's within contact with the
13:01:27 18 patient, it transfers energy by conductive means;
13:01:34 19 correct?
13:01:34 20 THE REPORTER: I'm sorry, you'll have to
21 state that again.
13:01:34 22 Q. When it transfers energy to the patient, it
13:01:34 23 does that by conductive means; correct?
13:01:37 24 MR. BLACKWELL: I object to the form of the
13:01:38 25 question.

13:01:39 1 A. In theory, that is correct.

13:01:49 2 Q. Well you guys measure that in your testing
13:01:52 3 when you put -- when you put the -- when --

13:01:54 4 When you justified changing to the 750,
13:01:57 5 checked the heat transfer, you put the blanket on top
13:02:00 6 of a -- a bed with many thermocouples; correct?

13:02:03 7 A. That's -- that's one of the --

13:02:05 8 Q. Okay.

13:02:05 9 A. -- tests that we used, but that only -- that
13:02:08 10 only measures temperature, that does not measure heat
13:02:11 11 transfer.

13:02:11 12 Q. [REDACTED]

13:02:14 13 [REDACTED]

13:02:17 14 [REDACTED]

13:02:19 15 [REDACTED]

13:02:22 16 [REDACTED]

13:02:25 17 [REDACTED]

13:02:30 18 [REDACTED]

13:02:34 19 [REDACTED]

13:02:37 20 [REDACTED]

13:02:40 21 [REDACTED]

13:02:43 22 [REDACTED]

13:02:45 23 [REDACTED]






































13:02:52 24 [REDACTED]

13:02:56 25 [REDACTED]

				139
13:02:56	1			
13:02:58	2			
13:03:00	3			
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13:04:03	24			
13:04:05	25			

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

			140
13:04:11	1	[REDACTED]	
13:04:15	2	[REDACTED]	
13:04:18	3	[REDACTED]	
13:04:20	4	[REDACTED] [REDACTED]	
13:04:22	5	[REDACTED]	
13:04:23	6	[REDACTED] [REDACTED] [REDACTED]	
13:04:29	7	[REDACTED]	
13:04:35	8	[REDACTED]	
13:04:37	9	[REDACTED] [REDACTED]	
13:04:40	10	[REDACTED]	
13:04:42	11	[REDACTED]	
13:04:44	12	[REDACTED]	
13:04:48	13	[REDACTED]	
13:04:49	14	[REDACTED] [REDACTED]	
13:04:50	15	[REDACTED]	
13:04:53	16	[REDACTED]	
13:04:54	17	[REDACTED] [REDACTED]	
13:04:55	18	[REDACTED] [REDACTED]	
13:04:56	19	[REDACTED] [REDACTED]	
13:04:59	20	[REDACTED]	
13:05:00	21	[REDACTED] [REDACTED]	
13:05:01	22	[REDACTED] [REDACTED]	
13:05:02	23	[REDACTED]	
13:05:06	24	[REDACTED]	
13:05:11	25	[REDACTED]	

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13:05:14	1		
13:05:16	2		
13:05:19	3		
13:05:19	4		
13:05:20	5		
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13:06:00	24		
13:06:01	25		

			142
13:06:04	1	Q. [REDACTED]	
13:06:08	2	[REDACTED]	
13:06:09	3	[REDACTED]	
13:06:11	4	[REDACTED]	
13:06:15	5	[REDACTED] [REDACTED]	
13:06:19	6	[REDACTED]	
13:06:23	7	[REDACTED]	
13:06:26	8	[REDACTED] [REDACTED]	
13:06:56	9	[REDACTED]	
13:06:57	10	[REDACTED]	
13:07:00	11	[REDACTED]	
13:07:02	12	[REDACTED]	
13:07:04	13	[REDACTED]	
13:07:06	14	[REDACTED] [REDACTED]	
13:07:07	15	[REDACTED] [REDACTED]	
13:07:14	16	[REDACTED] [REDACTED]	
13:07:16	17	[REDACTED]	
13:07:17	18	[REDACTED] [REDACTED]	
13:07:19	19	[REDACTED]	
13:07:22	20	[REDACTED]	
13:07:25	21	[REDACTED] [REDACTED]	
13:07:30	22	[REDACTED] [REDACTED]	
13:07:33	23	[REDACTED]	
13:07:37	24	[REDACTED]	
13:07:43	25	[REDACTED]	

			143
13:07:46	1	A. [REDACTED]	
13:07:50	2	[REDACTED]	
13:07:54	3	[REDACTED] [REDACTED]	
13:07:56	4	[REDACTED]	
13:07:59	5	[REDACTED]	
13:08:03	6	[REDACTED]	
13:08:05	7	[REDACTED]	
13:08:09	8	[REDACTED]	
13:08:12	9	[REDACTED] [REDACTED] [REDACTED]	
13:08:14	10	[REDACTED]	
13:08:17	11	[REDACTED] [REDACTED]	
13:08:21	12	[REDACTED]	
13:08:23	13	[REDACTED] [REDACTED]	
13:08:25	14	[REDACTED] [REDACTED]	
13:08:29	15	[REDACTED]	
13:08:32	16	[REDACTED]	
13:08:33	17	[REDACTED] [REDACTED]	
13:08:35	18	[REDACTED]	
13:08:39	19	[REDACTED]	
13:08:39	20	[REDACTED] [REDACTED]	
13:08:40	21	[REDACTED]	
13:08:41	22	[REDACTED] [REDACTED]	
13:08:44	23	[REDACTED]	
13:08:46	24	[REDACTED]	
13:08:48	25	[REDACTED]	

13:08:49 1 [REDACTED]

13:08:49 2 [REDACTED]

13:08:52 3 [REDACTED]

13:08:53 4 [REDACTED] [REDACTED]

13:08:54 5 [REDACTED]

13:08:55 6 [REDACTED] [REDACTED]

13:08:57 7 [REDACTED]

13:08:59 8 [REDACTED]

13:09:00 9 [REDACTED]

13:09:02 10 [REDACTED]

13:09:03 11 [REDACTED]

13:09:05 12 [REDACTED]

13:09:11 13 Q. Well you agree with me, to determine the --

13:09:15 14 the heat transfer, that you have to have knowledge on

13:09:20 15 how the blanket's used by healthcare providers;

13:09:24 16 correct?

13:09:24 17 MR. BLACKWELL: Object to the form of the

13:09:25 18 question.

13:09:29 19 A. We -- we place the blanket on a mannequin in

13:09:32 20 the way that we expect healthcare providers to use it

13:09:37 21 in the operating room.

13:09:37 22 Q. And how do you expect healthcare providers

13:09:40 23 to use it so you could test the mannequin?

13:09:42 24 A. We have instructions for use.

13:09:44 25 Q. Does anything go on top of the Bair Hugger?

13:09:46 1 A. Sometimes.

13:09:47 2 Q. Well when we say "sometimes," what -- what
13:09:51 3 goes on top of the Bair Hugger sometimes?

13:09:53 4 A. Occasionally a -- a blanket, sometimes a
13:09:57 5 drape, sometimes nothing.

13:09:59 6 Q. Would that blanket or drape have an effect
13:10:01 7 on the amount of contact the Bair Hugger has with the
13:10:03 8 patient?

13:10:05 9 A. It could.

13:10:05 10 Q. "It could." It does; doesn't it?

13:10:07 11 MR. BLACKWELL: I object to the form of the
13:10:09 12 question.

13:10:09 13 A. We've never measured it. I'm assuming that
13:10:11 14 it does.

13:10:27 15 MR. ASSAAD: Let's take a five-minute break
16 because I'm waiting for a printout of all the testing
13:10:32 17 that you referred to regarding the calculations.

13:10:32 18 THE WITNESS: Okay.

13:10:32 19 THE REPORTER: Off the record, please.

13:10:34 20 (Recess taken.)

13:18:59 21 BY MR. ASSAAD:

13:19:02 22 Q. With respect to the -- the calculations that
13:19:04 23 we were talking about before, do you know when those
13:19:05 24 were done with --

13:19:07 25 A. I don't recall what year I've worked on

13:19:13 1 those.

13:19:13 2 Q. Were they done for the 700 series or the 500
13:19:17 3 series?

13:19:17 4 A. I've probably done them for both, but I
13:19:24 5 don't remember what years. Certainly in the 1990s I
13:19:27 6 would have done some for the 500 series.

13:19:29 7 Q. Which would have -- would have been the heat
13:19:31 8 flux testing?

13:19:32 9 A. Is that the title of the test?

13:19:34 10 Q. I'm just asking was it the heat flux. Is
13:19:38 11 that what you were referring to?

13:19:40 12 A. It could be, yeah.

13:19:40 13 Q. All right. Was it -- was it done by Mark
13:19:42 14 Bie -- Bieberich?

13:19:42 15 A. Mark Bieberich could have done some of
13:19:44 16 those, yes.

13:19:45 17 Q. All right. With respect to the heat-
13:20:00 18 transfer improvement between the 750 -- the 700 series
13:20:05 19 and the 500 series, did you -- I --

13:20:11 20 You mentioned before the heat transfer was
13:20:13 21 better with the 700 series; correct?

13:20:14 22 A. Yes.

13:20:15 23 Q. To what -- to what extent? Like to what
13:20:18 24 quantity?

13:20:19 25 A. I -- I don't recall the amount by which it

13:20:22 1 was better.

13:20:22 2 Q. Was it -- do you have a rough --

13:20:24 3 Does 3M have a rough estimate? Was it twice
13:20:26 4 as good, 50 percent better, 30 percent better?

13:20:29 5 MR. BLACKWELL: Object to the form of the
13:20:30 6 question.

13:20:31 7 A. I don't recall the level of difference, only
13:20:32 8 that it was higher.

13:20:34 9 Q. Okay. And was the reasoning that it was
13:20:39 10 higher was because of the higher airflow or the
13:20:43 11 temperature control, or both?

13:20:44 12 A. Probably both, but the airflow probably
13:20:49 13 mattered more.

13:20:51 14 Q. Okay.

13:21:00 15 A. The reason I say that is that the
13:21:03 16 temperature difference probably isn't all that
13:21:06 17 significant after the patient's temperature -- skin
13:21:08 18 temperature warms up, but the h is -- does matter,
13:21:11 19 the -- the convective heat-transfer coefficient does
13:21:14 20 matter.

13:21:15 21 Q. Well -- well the h is convective, conductive
13:21:18 22 and radiant.

13:21:19 23 A. Well the -- the mannequin --

13:21:20 24 In the mannequin, in the in vitro testing,
13:21:23 25 we lump all of the coefficients in -- into one h,

13:21:27 1 That's true, but in -- but in reality it's the h from
13:21:31 2 the convective heat-transfer coefficient that matters
13:21:35 3 in live patients.

13:21:36 4 Q. And h is heat flux; correct?

13:21:37 5 A. h is the convective heat-transfer
13:21:40 6 coefficient.

13:21:42 7 Q. Okay. Well it could be conductive,
13:21:42 8 convective, or radiant; correct?

13:21:44 9 A. No. So for conductive it's K. It's the
13:21:48 10 thermoconductivity --

13:21:49 11 Q. Okay.

13:21:50 12 A. -- times the temperature difference, and for
13:21:52 13 radiation it's a Stefan-Boltzmann constant times some
13:21:56 14 other factors that are usually less than one.

13:22:00 15 Q. So for conductive it's K, for convective
13:22:03 16 it's h, and what was it for radiant? What's the
13:22:08 17 letter that --

13:22:08 18 A. Stefan-Boltzmann. Sigma.

13:22:11 19 Q. Sigma. Okay. And all those go into the
13:22:14 20 heat transfer; correct?

13:22:15 21 A. Those are coefficients that are multiplied
13:22:17 22 by the temperature difference, except for radiation
13:22:19 23 where it's temperature difference to the fourth power.

13:22:21 24 Q. Okay. But to calculate the heat transfer,
13:22:24 25 you have to calculate the total of all three of those,

13:22:27 1 of the K, the -- the Sigma and the h; correct?

13:22:29 2 A. If we were going to calculate it, yes.

3 Q. Okay.

13:22:33 4 A. However, we measure it with the mannequin,

13:22:35 5 we don't have to do any calculations --

6 Q. Okay. And the mannequin --

13:22:37 7 A. -- for our estimation.

13:22:39 8 Q. And the mannequin measures all three.

13:22:42 9 A. Yes.

13:22:42 10 Q. Okay. And the mannequin doesn't --

13:22:44 11 A. It -- it measures the effect of all three.

13:22:47 12 We can't -- we can't discriminate, really, which one

13:22:50 13 is which; it just treats them all the same, or

13:22:54 14 combines them all.

13:22:55 15 Q. So -- so since you can't discriminate which

13:22:59 16 one's which, you can't determine which portion of

13:23:01 17 the -- the heat transfer is a result of conductive,

13:23:04 18 convective, or radiant; correct?

19 MR. BLACKWELL: And I have --

13:23:06 20 Q. The exact -- the exact portion for heat

13:23:10 21 transfer.

13:23:10 22 MR. BLACKWELL: I have a con -- my

13:23:12 23 continuing objection to this whole line of questioning

13:23:13 24 as beyond the scope of the 30(b)(6) notice, and I

13:23:16 25 object to the form of the question beyond that.

13:23:17 1 Go ahead.

13:23:19 2 A. The -- the way that the individual
13:23:23 3 components were estimated was based on calculation,
13:23:26 4 not on measurement.

13:23:27 5 Q. So I'm going to give you what's been --
13:23:30 6 we'll mark as Exhibit No. --

13:23:32 7 THE REPORTER: 350.

13:23:33 8 Q. -- 350.

13:23:50 9 (Exhibit 350 was marked for
13:23:51 10 identification.)

13:23:51 11 BY MR. ASSAAD:

13:23:52 12 Q. What's been marked as Exhibit -- Exhibit 350
13:23:54 13 I represent is a list of all the testing -- well, a
13:23:59 14 testing log that was provided to us by 3M and Arizant.
13:24:03 15 It goes from 1995 until 2009.

13:24:09 16 Do you recognize this document?

13:24:10 17 A. Yes.

13:24:11 18 Q. What is --

13:24:12 19 In your own words, what is this document?

13:24:14 20 A. This is a log of all of the individual tests
13:24:19 21 that were conducted, mostly in the Research and
13:24:22 22 Development Department of Augustine and then Arizant.

13:24:24 23 Q. Would your calculations that you discussed
13:24:26 24 previously be -- be logged into this log?

13:24:28 25 A. Somewhere.

13:24:29 1 Q. Somewhere? Okay. Which one is your
13:24:32 2 calculations?

13:24:33 3 A. There's -- I mean this is, you know --
13:24:37 4 What is this, '95 to 2010? That's a --
13:24:41 5 those are years of --

13:24:42 6 I have no idea where it is in this log.

13:24:45 7 Q. Well I'd like you to look through it and let
13:24:47 8 me know where it is in the log, please.

13:24:48 9 A. I mean that could take all day.

13:24:50 10 MR. BLACKWELL: And for the record, the log
13:24:52 11 contains 691 entries and -- and it's 39 pages long.

13:24:58 12 Q. Well did you review this log in preparation
13:25:01 13 of today's deposition?

13:25:02 14 A. I did not.

13:25:03 15 Q. Would it be helpful -- would --

13:25:07 16 Would it be a search term you'd want to look
13:25:10 17 for that I could go on the computer and plug in a
13:25:13 18 search term to try to find it?

13:25:14 19 A. Heat flux, heat transfer, convective heat-
13:25:19 20 transfer coefficient, thermal conductivity.

13:25:33 21 Q. So if you go to item number 308 --
13:25:41 22 Are you there?

13:25:41 23 A. Yes.

13:25:42 24 Q. 2001, dated -- I guess test is October 9th,
13:25:47 25 2001, it states "Develop Forced-Air warming heat flux/

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13:25:50 1 convection coefficient test method." Would that be
13:25:53 2 one of the tests I could look at to see the
13:25:57 3 calculation to determine the -- to -- to support your
13:26:00 4 basis that the majority of the heat transfer is by
13:26:02 5 convective?

13:26:03 6 A. That's a good candidate.

13:26:05 7 Q. Would that be about the right time with
13:26:10 8 respect to the 750?

13:26:12 9 A. For the 750, yes. In 2001, yes.

13:26:15 10 Q. Well do you know how many calculations,
13:26:23 11 test -- like how many logs or how many calculations
13:26:25 12 were done with respect to that issue --

13:26:28 13 A. I don't --

13:26:29 14 Q. -- on the 700 series?

13:26:30 15 A. I don't know how many were done.

13:27:10 16 2002-085 would be a -- is a good candidate.

13:27:18 17 Q. Well two thous --

13:27:21 18 2002-85 is a review of Dr. Brauer paper on
13:27:30 19 forced-air warming blankets, not calculations you've
20 done; correct?

21 THE REPORTER: "...is a review of Dr." --

22 Q. Brauer, B-r-a-u-e-r, paper on forced-air
13:27:32 23 warming blanket heat flux. That's not calculations
13:27:32 24 that 3M did; correct?

13:27:34 25 A. But there -- there could easily be

13:27:37 1 calculations in that review.

13:27:38 2 Q. Well I'm asking: What calculations did 3M
13:27:41 3 perform with respect to heat transfer?

13:27:46 4 A. And -- and I've answered that we looked --
13:27:49 5 we estimated the contribution of convection,
13:27:52 6 conduction and -- well con -- convection and
13:27:55 7 radiation. We assumed the conduction was essentially
13:27:57 8 zero.

13:28:00 9 Q. [REDACTED]

13:28:03 10 [REDACTED]

13:28:04 11 [REDACTED]

13:28:14 12 [REDACTED]

13:28:22 13 [REDACTED]

13:28:27 14 Q. Well was a calculation ever made to the --
13:28:30 15 the -- what percentage of the forced-air warming
13:28:31 16 blanket is in contact with the patient?

13:28:33 17 A. No.

13:28:34 18 Q. Wouldn't that be needed to determine
13:28:36 19 conductive heat transfer?

13:28:39 20 A. Not when we assumed that it was virtually
13:28:42 21 zero.

13:28:43 22 Q. That wasn't my question.

13:28:44 23 Wouldn't that information be needed to
13:28:46 24 determine the amount of conductive heat transfer from
13:28:48 25 the forced-air warming blanket to the patient? "Yes"

13:28:50 1 or "no."

13:28:50 2 A. It would be one of --

13:28:51 3 MR. BLACKWELL: I object as asked and

13:28:53 4 answered.

13:28:53 5 Q. "Yes" or "no."

13:28:53 6 A. It would be one of the variables needed to

13:28:56 7 know to make that calculation.

13:28:57 8 Q. Okay. A necessary variable.

13:28:59 9 A. Yes.

13:29:00 10 Q. And that wasn't done by 3M; correct?

13:29:03 11 A. Correct.

13:29:05 12 Q. What is the Brauer test plan for heat

13:30:35 13 transfer?

13:30:36 14 A. Dr. Brauer is an anesthesiologist in Germany

13:30:39 15 who developed an in vitro method for measuring heat

13:30:43 16 transfer of -- of forced-air warming systems, and

13:30:49 17 we -- I actually flew out to speak to him and then

13:30:54 18 came back and took his paper and we designed a test

13:30:59 19 fixture that -- modeled after his paper to do our own

13:31:05 20 heat-transfer testing.

13:31:22 21 Q. Is there a test that you're aware of that

13:31:24 22 compares the heat flux or the heat transfer between

13:31:28 23 the 750 and the 500 series?

13:31:30 24 A. I -- I'm certain that there is, but there's

13:31:41 25 no way that I can remember what number -- what the

13:31:43 1 number was for that test.

13:31:46 2 Q. Well when you -- I mean you just --

13:31:49 3 You made the design changes to the 750 and
13:31:52 4 one of the big design changes was the airflow. When
13:31:57 5 you brought the 750 to market, did you indicate that
13:32:06 6 the increased airflow is much better than the 500 and
13:32:08 7 it gives you this much more heat transfer?

13:32:11 8 A. Oh, I don't remember what the marketing
13:32:14 9 materials stated about the 750. I mean it was an
13:32:19 10 improvement; we certainly presented it as an
13:32:23 11 improvement over the existing warming units.

13:32:33 12 Q. And correct me if I'm wrong, but the
13:32:36 13 advantage -- or the justification of putting the
13:32:39 14 therm -- temperature sensor at the end of the hose is
13:32:43 15 that the temperature coming out of the blanket is
13:32:48 16 going to be much closer to 42 degrees Celsius in the
13:32:52 17 750 than it would be in the 500 series; correct?

13:32:55 18 A. No, that's not true. It's not correct.

13:32:57 19 Q. Then what was the purpose --

13:32:59 20 What was the justification for putting a
13:33:01 21 temperature sensor at the end of the hose?

13:33:02 22 A. The -- the purpose of doing that was to
13:33:05 23 minimize the temperature variance that occurs in rooms
13:33:09 24 that are cold versus rooms that are warm, so if
13:33:13 25 the -- on the --

13:33:14 1 The model 500 series are calibrated at a
13:33:19 2 fixed ambient temperature. If that ambient
13:33:21 3 temperature changes significantly, then the air
13:33:23 4 temperature at the end of the duct -- duct also
13:33:27 5 changes. In the 750 and the 775, it doesn't make any
13:33:33 6 difference what the ambient temperature of the room is
13:33:35 7 because the radiant heat losses from the duct are made
13:33:38 8 up by increasing the power to the heater in response
13:33:41 9 to those losses. So it -- it's much more robust and
13:33:46 10 resistant to temperature changes in -- in air in rooms
13:33:50 11 that change their ambient temperature.

13:33:52 12 Q. So it would increase the accuracy of the
13:34:04 13 temperature leaving the duct regardless of the ambient
13:34:12 14 temperature. That was the advantage.

13:34:18 15 A. Well --

13:34:18 16 Q. That was a bad question.

13:34:19 17 A. Okay.

13:34:20 18 Q. Let me try to understand this in layman's
13:34:22 19 terms. You might lose some -- you might lose some
13:34:26 20 temperature as a result of -- of radiant heat while
13:34:30 21 the air is in the duct as a result of the difference
13:34:32 22 in ambient room temperature.

13:34:34 23 A. That's right.

13:34:34 24 Q. Okay. And by putting the temperature sensor
13:34:36 25 at the end of the duct, you could take that into

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13:34:40 1 account and ensure that the temperature coming out of
13:34:43 2 the duct is 43 degrees regardless of what the ambient
13:34:47 3 temperature is set in the room.

13:34:49 4 A. That's correct.

13:34:50 5 Q. Okay. And as a result of that improvement,
13:34:56 6 you can control the temperature coming out of the
13:35:00 7 blanket much better and therefore increase heat
13:35:04 8 transfer.

13:35:04 9 A. Especially in cold ambient temperatures.

13:35:08 10 Q. Which is very common in a -- in an operating
13:35:10 11 room environment.

13:35:11 12 A. Yes.

13:35:11 13 Q. The 500 series, you'd have to use a test kit
13:35:16 14 to -- to calibrate at a certain temperature, but if
13:35:19 15 the temperature was changed, there's no -- that 500
13:35:22 16 series is no longer calibrated for that ambient
13:35:25 17 temperature.

13:35:25 18 A. That's correct.

13:35:26 19 Q. Besides airflow and --

13:36:20 20 We talked about airflow, we talked about the
13:36:23 21 three heat coils, the temperature sensor. Any other
13:36:31 22 significant changes or -- design changes with respect
13:36:34 23 to functionality between the 700 series and the 500
13:36:39 24 series?

13:36:40 25 A. Yes.

13:36:43 1 Q. What are they?

13:36:44 2 A. The control scheme is managed by a -- a
13:36:50 3 microprocessor on the 700 series warming units. The
13:36:53 4 500 series control scheme is all an individual
13:36:59 5 component, electronic component; there are no
13:37:04 6 microprocessors involved.

13:37:05 7 Q. So it's a smarter machine.

13:37:06 8 A. It has more capability, yes.

13:37:08 9 Q. Going back to the heat transfer, when you
13:37:35 10 did the heat-transfer calculations on, I guess, the --
13:37:39 11 the Brauer -- Brauer --

13:37:41 12 A. Brauer.

13:37:42 13 Q. -- Brauer, I guess, or -- or the -- the test
13:37:45 14 bed, the mannequin test bed, you would agree with me
13:37:50 15 that with respect to the different types of heat
13:37:52 16 transfer -- conductive, radiant and convective -- it
13:37:59 17 also depends what type of blanket is being used;
13:38:02 18 correct?

13:38:02 19 A. You mean the relative amounts --

13:38:06 20 Q. Yes.

13:38:07 21 A. -- of each of those?

13:38:08 22 It could -- it could change depending on the
13:38:10 23 blanket.

13:38:10 24 Q. Like, for example, an underbody blanket
13:38:12 25 where someone lays on top of, there's a lot more

13:38:15 1 conductive energy transfer; correct?

13:38:17 2 A. No.

13:38:17 3 Q. No? There's no more --

13:38:19 4 There's no contact?

13:38:20 5 A. Oh, there's contact.

13:38:21 6 Q. Okay.

13:38:21 7 A. Yeah.

13:38:22 8 Q. I mean the weight of the patient is laying

13:38:24 9 on top of the blanket; correct?

13:38:26 10 A. Right. But the blankets are designed to
13:38:29 11 completely eliminate any communication of the heated
13:38:32 12 air to the areas where the blanket's compressed. So
13:38:35 13 an underbody blanket, a forced-air underbody blanket
13:38:40 14 does not warm under the body, it only warms on the
13:38:43 15 lateral surfaces of the body. There is no -- there is
13:38:46 16 no heat transfer on the posterior surface of the body.

13:38:49 17 Q. Is it your test --

13:38:50 18 Is it 3M's testimony today that the air that
13:38:54 19 the underbody blanket is on is not heated inside the
13:38:57 20 blanket?

13:38:58 21 A. No, that's not what I said. The --

13:38:59 22 My testimony is that the blanket, when it's
13:39:03 23 compressed --

13:39:03 24 Q. Well I want 3M'S testimony. Not your
13:39:06 25 testimony, 3M's testimony.

13:39:08 1 A. Okay.

2 Q. Okay?

13:39:08 3 A. Testimony --

13:39:09 4 The testimony is that when the blanket is
13:39:11 5 compressed, there is no air being ejected in the area
13:39:14 6 where the blanket is compressed, and therefore there's
13:39:17 7 no -- there's no net heat transfer into the posterior
13:39:20 8 surface of the body. Underbody blankets warm by
13:39:23 9 blowing air on the lateral surfaces of the body.

13:39:43 10 Q. And what internal testing was -- is there --

13:39:46 11 Is there different internal testing with
13:39:47 12 respect to the heat transfer for the different
13:39:49 13 blankets?

13:39:49 14 A. I'm not sure I understood that question.

13:39:53 15 Q. Well I want to know: Is there internal
13:39:55 16 testing in this document -- you don't have to look
13:39:57 17 through it -- with respect to the different heat
13:39:59 18 transfer between the blankets using the 750 model and
13:40:06 19 the 500 model?

13:40:08 20 A. Yes, I believe there is.

13:40:09 21 Q. So every blanket goes through this testing
13:40:12 22 with respect to the heat transfer?

13:40:13 23 A. Yes.

13:40:24 24 Q. What is it about the increased airflow that
13:41:11 25 increases -- that makes the 750 better at heat

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13:41:15 1 transfer than the 500 series that justified the design
13:41:20 2 change?

13:41:20 3 A. Convective heat transfer is proportional to
13:41:27 4 the product of h , which is the convective heat-
13:41:29 5 transfer coefficient, and the temperature difference
13:41:32 6 between T_{∞} and T_{surface} , that is the surface
13:41:36 7 temperature of the body, and T_{∞} is the
13:41:39 8 temperature of the blanket, so increasing h , which
13:41:44 9 is -- depends directly on the velocity of the air
13:41:47 10 exiting the blanket, is -- is a multiplier effect if
13:41:51 11 you have a constant temperature difference.

13:41:58 12 Q. So increasing h changes your ΔT ?

13:42:02 13 A. No. ΔT is fixed by the -- by the
13:42:07 14 warming unit, the heater. h is -- h is only
13:42:12 15 proportional to airflow velocity.

13:42:15 16 Q. So what's the equation? Do you have the
13:42:17 17 equation?

13:42:18 18 A. Q is equal to $hA(\Delta T)$.

13:42:22 19 Q. And what's A stand for?

13:42:24 20 A. Area, the area over which the heat transfer
13:42:27 21 occurs. You can do Q over A is equal to $h(\Delta T)$.

13:42:31 22 Q. And h is the --

13:42:32 23 A. Convective heat-transfer coefficient.

13:42:34 24 Q. Okay. And -- and ΔT is the temperature
13:42:38 25 and Q is --

13:42:39 1 A. Q is the heat-transfer rate.

13:42:40 2 Q. Okay. Okay. You have -- you have the
13:42:52 3 analytical data by doing physical tests over the
13:42:55 4 mannequin; correct?

13:42:59 5 A. To do what? I'm not --

13:43:00 6 Q. Like when you calculate the heat transfer,
13:43:02 7 you have that data from -- from your actual, real-life
13:43:06 8 testing on the mannequin; correct?

13:43:08 9 A. The -- the mannequin is able to determine h
13:43:12 10 and it's able to determine delta T.

13:43:14 11 Q. Okay.

13:43:15 12 A. And we have to compute Q, obviously. And A,
13:43:17 13 we have to estimate that.

13:43:19 14 Q. Well you keep on saying the mannequin
13:43:22 15 determines h, but it determines also K and epsilon;
13:43:25 16 correct?

13:43:25 17 A. No, it doesn't do that.

13:43:27 18 Q. Why not?

13:43:27 19 A. Well because epsilon is a -- is a material
13:43:31 20 property and K is also a material property. The
13:43:35 21 mannequin doesn't do that.

13:43:37 22 Q. Well the mannequin --

13:43:38 23 A. We have to know those material properties.

13:43:40 24 Q. I understand. But when you calculate the
13:43:42 25 heat-transfer rates and the temperature difference

13:43:44 1 that the mannequin calculates, the temperature

13:43:46 2 difference is based on convective, conductive, and

13:43:48 3 radiant.

13:43:49 4 A. Yes.

13:43:49 5 Q. Okay.

13:43:50 6 A. That's true.

13:43:50 7 Q. So that's what the mannequin is calculating,
13:43:52 8 all those put together.

13:43:53 9 A. Yes.

13:43:53 10 Q. Okay. Let's stay on that. Because you're
13:43:55 11 saying the mannequin calculates h, but it doesn't

13:43:58 12 really calculate h, it's calculating the total heat

13:44:01 13 transfer with respect to all three modalities of heat

13:44:04 14 transfer.

13:44:05 15 A. It -- it calculates a lumped h, --

16 Q. Okay.

13:44:08 17 A. -- which calculates all of those.

13:44:10 18 Q. Okay. Was there ever a calculation -- since

13:44:14 19 you know the airflow, the delta T, the amount of heat

13:44:17 20 transfer based on a mannequin -- as to what percentage

13:44:20 21 was based on radiant heat transfer, conductive heat

13:44:28 22 transfer, or convective heat transfer? Was that

13:44:30 23 calculation ever done by 3M?

13:44:31 24 A. Radiant and convective, yes. Conductive,

13:44:34 25 no.

13:44:35 1 Q. What percentage of the heat transfer is
13:44:37 2 involved with radiant?

13:44:38 3 A. Depending on the blanket, around 40 percent.

13:44:41 4 Q. So 40 percent of the heat transfer was
13:44:44 5 radiant?

13:44:44 6 A. Thirty to 40 percent.

13:44:46 7 Q. And ra --

13:44:47 8 And what is radiant heat transfer?

13:44:50 9 A. It's the transfer of energy by
13:44:53 10 electromagnetic radiation from a -- from one surface
13:44:57 11 to another.

13:44:58 12 Q. And is that exclusive of forced-air warming,
13:45:01 13 or any heating device?

13:45:04 14 MR. BLACKWELL: I object to the form of the
13:45:06 15 question.

13:45:08 16 A. Well any -- any device that is at a -- a
13:45:10 17 temperature that differs from the surface temperature
13:45:13 18 of the human body and is separated by some distance
13:45:16 19 can transfer heat by radiation.

13:45:18 20 Q. So as long as there's a delta T, there's a
13:45:23 21 heat transfer by radiation.

13:45:25 22 A. As -- as long as there's no --

13:45:28 23 As long as the two materials are not
13:45:30 24 touching each other.

13:45:30 25 Q. Okay. So if 40 percent is by radiant heat,

13:45:57 1 60 percent, you would agree with me, is by conductive
13:46:00 2 and convective.

13:46:01 3 A. Well I --

13:46:03 4 Q. We don't know what percentage of the 60, but
13:46:06 5 it has to be 60 percent by conductive and convective;
13:46:08 6 correct?

13:46:08 7 A. Okay. Yes.

13:46:10 8 Q. And sitting here today, you don't know what
13:46:13 9 percentage of the heat transfer is by conductive or
13:46:15 10 convective, the exact number.

13:46:18 11 MR. BLACKWELL: Object to the form of the
13:46:18 12 question.

13:46:19 13 A. The exact number I do not know.

13:46:20 14 Q. Okay. How did you calculate the radiant
13:47:02 15 heat of 40 percent?

13:47:04 16 A. Radiant heat transfer is the product of a
13:47:14 17 couple of factors, a -- a -- a -- a view factor, an
13:47:21 18 elevation factor, the Stefan-Boltzmann constant times
13:47:27 19 the -- the temperature difference in absolute
13:47:30 20 thermodynamic temperatures to the fourth power, so
13:47:33 21 it's -- it's easily computable.

13:47:41 22 Q. All right. All right. I'll move on. I
13:48:15 23 might come back to this in a little bit. They're
13:48:19 24 looking some stuff up for me.

13:48:21 25 But let's go into the next subject area,

13:48:23 1 which is internal testing performed by the defendants
13:48:25 2 to evaluate the Bair Hugger patient warming system, or
13:48:29 3 any component thereof, that disrupts the sterile
13:48:29 4 surgical field, disperse airborne particles and/or
13:48:33 5 pathogens, harbor bacteria inside the device, or cause
13:48:37 6 surgical-site infections.

13:48:44 7 MR. BLACKWELL: Number six, Gabe.

13:48:45 8 MR. ASSAAD: Number six.

13:48:46 9 Q. I'll willing to go specifically one by one,
13:48:48 10 and we're --

13:48:49 11 Let's list out, before we talk about it, the
13:48:51 12 internal testing. So what internal testing which was
13:48:55 13 done by 3M with respect to the Bair Hugger warming
13:48:59 14 system, or any component thereof, to disrupt the
13:49:02 15 sterile surgical field? Internal.

13:49:09 16 A. We conducted a number of evaluations using
13:49:16 17 Schlieren imaging to look at the effect that the
13:49:24 18 temperature of the various blankets had on airflow in
13:49:28 19 laminar airflow settings. This was a -- a test
13:49:32 20 fixture, this wasn't an operating room or even a
13:49:37 21 simulation of an operating room, it was a test fixture
13:49:39 22 with laminar airflow that we used to evaluate that.

13:49:43 23 Q. And that was done at 3M's facility; correct?

13:49:46 24 A. Yes.

13:49:47 25 Q. That wasn't done before the -- the

13:49:50 1 commercialization of the 700 series; correct?

13:49:52 2 A. It was done after the commercialization of
13:49:56 3 the 700.

13:49:57 4 Q. It was actually done after the purchase of
13:49:59 5 Arizant by 3M.

13:50:00 6 A. Yes.

13:50:01 7 Q. Okay. And that was done at a 3M lab;
13:50:05 8 correct?

13:50:05 9 A. Yes.

13:50:05 10 Q. What year was that done?

13:50:09 11 A. I believe it was done in 2010 or 2011.

13:50:11 12 Q. Okay. Why was it done?

13:50:12 13 A. Because of the questions that were raised
13:50:19 14 about the potential for laminar airflow disruption in
13:50:24 15 operating rooms.

13:50:25 16 Q. And who was -- and who was it done by?

13:50:28 17 A. Gary Hansen. I was there. Daniel Japutnich
13:50:35 18 was there; it was his laboratory.

13:50:38 19 Q. And what's his title?

13:50:39 20 A. Well he was a corporate scientist I believe.
13:50:43 21 He's retired now.

13:50:49 22 Q. Do you know why he retired?

13:51:02 23 A. Well I suspect that he wanted to.

13:51:06 24 Q. Okay. So you said --

13:51:09 25 And to do that Schler --

13:51:10 1 Is it Schlieren?

13:51:11 2 A. Schlieren.

13:51:12 3 Q. -- Schlieren imaging, you have to have a

13:51:15 4 special camera; correct?

13:51:15 5 A. No.

13:51:15 6 Q. How is it done?

13:51:16 7 A. Use a -- a lens, a special lens that allows

13:51:22 8 you to look at variations in the -- I guess the

13:51:28 9 refractive index of air as it changes -- as it --

13:51:32 10 Air with different temperatures has

13:51:33 11 different refractive indices, and you can see the

13:51:36 12 waves of the air based on the -- the temperature.

13:51:44 13 Q. And this was not done in -- in an operating

13:51:47 14 room setting; correct?

13:51:48 15 A. No. It was done in a laboratory.

13:51:49 16 Q. Okay. And you said you simulated the

13:51:51 17 laminar flow of an operating room?

13:51:54 18 A. Yes.

13:51:55 19 Q. How was that done?

13:51:56 20 A. With a test fixture that had nozzles that --

13:52:02 21 that we could control airflow in so that the air

13:52:07 22 was lam -- airflow was laminar over a large area in

13:52:10 23 the test fixture.

13:52:12 24 Q. What was the Reynolds number of the airflow?

13:52:14 25 A. Less than 3,000.

13:52:17 1 Q. What was the rate of the airflow?

13:52:19 2 A. I don't know.

13:52:20 3 Q. How do you know it was less than 3,000?

13:52:22 4 A. Because it was laminar.

13:52:24 5 Q. How did you know it was laminar?

13:52:27 6 A. We -- we did calculations to make sure that
13:52:27 7 it was laminar.

13:52:28 8 Q. How did you calculate it?

13:52:30 9 A. There are -- there are calculations to look
13:52:32 10 at airflow rates and, you know, to make sure that
13:52:37 11 the -- the Reynolds number in the area that we were
13:52:40 12 testing is under 3,000.

13:52:42 13 Q. Do you think the Reynolds number in an
13:52:47 14 operating room is less than 3,000?

15 THE REPORTER: I'm sorry.

16 Q. Do you think the Reynolds number in an
13:52:48 17 operating room is less than 3,000?

13:52:48 18 A. In a laminar airflow where it's not
13:52:53 19 disturbed, probably.

13:52:54 20 Q. So you're at the --

13:52:58 21 Who came up with the testing idea to do the
13:53:00 22 Schlieren imaging?

13:53:01 23 A. I think it was Gary Hansen and -- and Dan
13:53:05 24 Japutnich.

13:53:06 25 Q. Okay. And were you part of the calculations

13:53:10 1 to determine that the airflow was laminar?

13:53:12 2 A. No, I was not.

13:53:13 3 Q. Okay. Who did those calculations?

13:53:15 4 A. Either Gary Hansen or Dan Japutnich.

13:53:19 5 Q. Did Gary Hansen have the ability to do those
13:53:24 6 calculations?

13:53:24 7 A. Yes. He's an engineer, fully qualified.

13:53:25 8 Q. Did you review those documents in
13:53:32 9 preparation of today's testimony?

13:53:33 10 A. I did not.

13:53:38 11 Q. You'd agree with me that there is -- that
13:53:41 12 the reflective index of the air above the Bair Hugger
13:53:45 13 blanket on the Schlieren imaging shows that there was
13:53:50 14 an effect on the unidirectional airflow; correct?

13:53:51 15 MR. BLACKWELL: Object to the form of the
13:53:52 16 question.

13:53:53 17 A. Would you restate it? I'm sorry.

13:53:55 18 Q. You would agree with me that there was an
13:53:58 19 effect on the imaging, if it's the one I'm thinking
13:54:00 20 about that I've seen that was produced, there was an
13:54:03 21 effect on the unidirectional airflow by the Bair
13:54:06 22 Hugger blanket.

13:54:07 23 MR. BLACKWELL: I object to the form of the
13:54:08 24 question.

13:54:08 25 A. In the test fixture that we put up, yes.

13:54:11 1 Q. There was -- there was an effect on the
13:54:13 2 unidirectional airflow; correct?

13:54:15 3 A. Yes.

13:54:16 4 Q. Any other studies that you did to test
13:54:17 5 the -- whether or not the Bair Hugger patient warming
13:54:22 6 system disrupts the -- the sterile surgical field?
13:54:25 7 Internally.

13:54:26 8 A. Not to my recollection.

13:54:40 9 Q. So the first time 3M did a test regarding
13:54:45 10 whether or not any of its devices disrupted the
13:54:49 11 sterile surgical field was in either 2010 or 2011,
13:54:52 12 internally.

13:54:53 13 A. No. We had conducted a study in Amersfoort,
13:55:03 14 Holland to look at the effect of Bair Hugger on
13:55:05 15 laminar airflow before --

13:55:06 16 Q. Was that done internally?

13:55:07 17 A. Oh, no. Sorry. But I mean it was in a --
13:55:09 18 it was a --

13:55:10 19 It wasn't done in a laboratory. Right.

13:55:11 20 Q. I'm saying --

13:55:12 21 A. It was conducted by Arizant in a hospital
13:55:14 22 setting.

13:55:15 23 Q. And hired Sessler to publish it.

13:55:18 24 A. We hired a company, LUWA I believe it was,
13:55:20 25 to do the study.

13:55:22 1 Q. And who wrote the manuscript?

13:55:24 2 A. Dan Sessler and Olmstead and the authors of
13:55:30 3 the paper.

13:55:30 4 Q. And Gary Hansen?

13:55:31 5 A. I don't believe Gary Hansen wrote it.

13:55:34 6 Q. Okay. Now that wasn't an internal test,
13:55:36 7 that was an external test; correct?

13:55:38 8 MR. BLACKWELL: I object to the form of the
13:55:39 9 question.

13:55:39 10 Q. That was -- that was done by a third party.

13:55:40 11 A. It was.

13:55:41 12 MR. BLACKWELL: Same objection.

13:55:42 13 Q. Okay. That -- that's number seven when we
13:55:44 14 talk about external testing. We're still on number
13:55:48 15 six.

13:55:49 16 So the only testing done by 3M with respect
13:55:51 17 to the Bair Hugger device disrupting the sterile
13:55:53 18 surgical field was done in 2010-2011.

13:55:57 19 A. Gary Hansen and I had done -- previously
13:56:03 20 done some Schlieren analysis in our lab at Arizant
13:56:09 21 before the acquisition.

13:56:10 22 Q. What year was that?

13:56:12 23 A. 2009 or '10.

13:56:15 24 Q. I did not see that. Did -- was that in your
13:56:18 25 files or was that --

13:56:18 1 Did you review those documents in
13:56:20 2 preparation of today's testimony?

13:56:21 3 A. I did not.

13:56:22 4 Q. Okay. Where did you guys get a Schlieren
13:56:27 5 lens from? Schlieren lens.

13:56:28 6 A. From some -- a laboratory supply company.

13:56:32 7 Q. What's the name of the supply company?

13:56:34 8 A. Edmund Scientific.

13:56:39 9 Q. Okay. What was the result of those -- that
13:56:42 10 testing done in 2009-2010?

13:56:44 11 A. I believe they were inconclusive.

13:56:46 12 Q. Inconclusive. Okay. Besides the one in --
13:56:55 13 the --

13:56:57 14 Besides Schlieren testing done in 2009-2010,
13:57:00 15 before the acquisition of Arizant by 3M, and the one
13:57:04 16 done while -- after the acquisition of Arizant by 3M
13:57:07 17 in 2010 or 2011, are there any other internal testing
13:57:11 18 done to determine whether or not the Bair Hugger
13:57:14 19 warming unit disrupts the sterile surgical field?

13:57:17 20 A. I don't believe so.

13:57:19 21 Q. So the answer to my question is "no."

13:57:21 22 A. "No."

13:57:21 23 Q. Okay. Mr. Van Duren, we don't have the
13:57:54 24 2009-2010 Schlieren studies, and I'd like to ask some
13:57:57 25 questions about it. Is there any way you could get a

13:57:58 1 copy of that and send it to me today?

13:58:00 2 MR. BLACKWELL: I don't think so, but we can
13:58:01 3 talk about it off the record.

13:58:04 4 Are you getting ready to otherwise go into
13:58:05 5 another subject? Is this a good time for a break?

13:58:07 6 MR. ASSAAD: I'm still --

13:58:08 7 I mean I'm staying on number six. I only
13:58:11 8 did part one of number six. But if you want a break,
13:58:13 9 we can take a break.

13:58:15 10 MR. BLACKWELL: Yeah. I mean at this point,
13:58:16 11 sitting here, I don't know what's been asked for,
13:58:17 12 what's been produced --

13:58:18 13 MR. ASSAAD: Well we asked for all testing,
13:58:20 14 and you guys produced a 2011 Schlieren.

13:58:22 15 MR. BLACKWELL: Well I hear you're saying
13:58:24 16 that, but I don't have anything in front of me to show
13:58:25 17 me what you asked for, I don't know --

13:58:27 18 MR. ASSAAD: Okay.

13:58:27 19 MR. BLACKWELL: -- what it is you received,
13:58:29 20 so it's hard to answer.

13:58:29 21 MR. ASSAAD: So the answer to my question is
13:58:30 22 no, you're not going to produce it today.

13:58:33 23 We'll -- we'll demand production --

24 MR. BLACKWELL: Well if you -- if you'd
25 like --

13:58:33 1 MR. ASSAAD: -- a supplement of our
13:58:36 2 production.

13:58:36 3 MR. BLACKWELL: -- to supply my answer, you
13:58:36 4 could feel free to do so, but I think I gave you my
13:58:39 5 own.

13:58:39 6 MR. ASSAAD: We asked for all testing. We
13:58:41 7 haven't got this one. I'm just trying to expedite
13:58:43 8 things so we don't have to come back another day,
13:58:47 9 because I'm going to leave the deposition open
13:58:49 10 regarding the Schlieren testing that we have not
13:58:53 11 received. And maybe it's part of a document that we
13:58:54 12 have received, but I have not seen it and none of us
13:58:55 13 have seen it, and so if you know what he's referring
13:58:58 14 to and it's been produced, it might be helpful. If
13:59:00 15 you don't know, that's fine, we could address it at a
13:59:04 16 different time.

13:59:05 17 Do you want a break or -- or not?

13:59:08 18 MR. BLACKWELL: Yeah, let's -- let's take --

13:59:08 19 MR. ASSAAD: Okay. Let's go on a break.

13:59:09 20 MR. BLACKWELL: Let's take a break. And
13:59:11 21 Gabe, if you describe it, I will send an e-mail and
13:59:13 22 ask the team.

13:59:14 23 THE REPORTER: Off the record, please.

24 (Recess taken.)

25 BY MR. ASSAAD:

14:13:35 1 Q. Mr. Van Duren, before off the record we
14:13:37 2 discussed a 2009-2010 Schlieren test that was done by
14:13:43 3 you at Arizant before the acquisition of Arizant by
14:13:48 4 3M. Do you recall that testimony?

14:13:49 5 A. Yes.

14:13:49 6 Q. And it's my understanding that you -- you
14:13:52 7 did -- you did Schlieren imaging but you did not
14:13:57 8 create a report.

14:13:58 9 A. That's correct.

14:13:59 10 Q. Did you take pictures of the imaging?

14:14:03 11 A. I don't believe we took pictures at the
14:14:05 12 time.

14:14:05 13 Q. Okay. And who requested this type of
14:14:13 14 internal testing?

14:14:14 15 A. It wasn't requested. This was an internal
14:14:19 16 experimentation with a -- a new lens to do Schlieren
14:14:23 17 photography, so we were -- or Schlieren imaging, so we
14:14:26 18 were experimenting with it.

14:14:27 19 Q. When you say "we," it would be Arizant,
14:14:33 20 correct, --

14:14:33 21 A. Yes.

14:14:34 22 Q. -- at that time?

14:14:34 23 A. Gary Hansen and I.

14:14:35 24 Q. Who came up with the idea, you or Gary
14:14:38 25 Hansen, with this Schlieren testing?

14:14:40 1 A. Gary Hansen.

14:14:41 2 Q. And did you purchase the -- the Schlieren
14:14:46 3 lens or did you just rent it?

14:14:47 4 A. We bought it.

14:14:48 5 Q. Do you still have it today?

14:14:50 6 A. I haven't seen it. It's probably in the
14:14:52 7 laboratory somewhere.

14:14:53 8 Q. Okay. And you said the results were
14:14:57 9 inconclusive.

14:14:58 10 A. I -- I'm not even sure we were doing any
14:15:01 11 testing. We were learning how to use the -- the new
14:15:05 12 lens and the new in -- instrumentation.

14:15:08 13 Q. So what -- what Bair Hugger model was used?

14:15:11 14 A. I'm not even --

14:15:12 15 Q. 750?

14:15:13 16 A. I'm not even sure we used the Bair Hugger.

14:15:15 17 Q. So when I asked for internal testing and you
14:15:18 18 referred to the 2009-2010 Schlieren testing, what were
14:15:22 19 you testing, if anything, besides how to use the
14:15:26 20 Schlieren lens?

14:15:27 21 A. We may have used a -- may have used a Bair
14:15:31 22 Hugger blanket to heat a surface to measure the change
14:15:35 23 in the refractive index of the air above that, but I
14:15:39 24 believe we used -- I believe we used some conductive
14:15:42 25 blankets and probably we did use some Bair Hugger

14:15:45 1 blankets as well, I just -- again, I --

14:15:48 2 We didn't document it. I don't have a clear
14:15:49 3 recollection of what we did, but it was more of a way
14:15:53 4 for us to learn how to use the Schlieren lens and
14:15:59 5 projector.

14:16:00 6 Q. And -- and when you look through a Schlieren
14:16:03 7 lens, what exactly are you seeing?

14:16:05 8 A. You see an image of the boundary of the air
14:16:14 9 that has different refractive indices mixing, so it
14:16:18 10 looks like a -- looks like steam rising, or smoke.

14:16:23 11 Q. Okay. And that --

14:16:25 12 Is it based on the -- the refractive
14:16:28 13 indic -- index -- indices on the density of the air?

14:16:32 14 A. Yes, I believe that's correct.

14:16:34 15 Q. Okay. And you said you tested it on a
14:16:43 16 conductive blanket?

14:16:44 17 A. Yes, I believe we did.

14:16:45 18 Q. What conductive blanket?

14:16:46 19 A. I believe it was a Geratherm, but it could
14:16:50 20 have been a Hot Dog.

14:16:52 21 Q. And does --

14:16:53 22 The Schlieren imaging, you could see
14:17:02 23 different types of heat transfer; correct?

14:17:04 24 A. It's not really heat transfer that you're
14:17:10 25 observing, it's merely the air movement caused by the

14:17:15 1 different densities.

14:17:17 2 Q. And the air movement is caused by the heat
14:17:20 3 transfer into the air.

14:17:22 4 MR. BLACKWELL: Object to the form of the
14:17:23 5 question.

14:17:25 6 A. It -- it's caused by the air being heated by
14:17:28 7 whatever mechanism, whatever --

14:17:31 8 Yes.

14:17:31 9 Q. Because when you heat air, it changes the
14:17:33 10 density and therefore you could see the different
14:17:35 11 refraction indices on the Schlieren -- in -- on the
14:17:40 12 Schlieren lens; correct?

14:17:41 13 A. That's correct.

14:17:44 14 Q. And did you compare the differences between
14:17:48 15 the conductive blanket and forced-air warming blanket?

14:17:51 16 A. I believe we observed them. I can't say
14:17:55 17 that we compared them.

14:17:56 18 Q. Because it's really difficult to have a
14:17:59 19 measurement. It's just more of an observation by a --
14:18:01 20 visual observation than any sort of measurement,
14:18:04 21 correct, the Schlieren imaging?

14:18:06 22 MR. BLACKWELL: Object to the form of the
14:18:07 23 question, beyond the scope of the 30(b)(6)
14:18:10 24 designation.

14:18:10 25 A. The Schlieren is more of a qualitative

14:18:12 1 measure.

14:18:14 2 Q. You could see a change, but you can't
14:18:16 3 quantify the change.

14:18:17 4 MR. BLACKWELL: Same objection.

14:18:18 5 A. There -- there may be a way to quantify it.
14:18:22 6 We've never done that.

14:18:23 7 Q. Okay. And you tested it on the -- on -- on
14:18:26 8 a Bair Hugger blanket. Do you know which one?

14:18:28 9 A. I don't know which one.

14:18:29 10 Q. And do you know what --

14:18:30 11 You don't know which model Bair Hugger
14:18:32 12 blower was used.

14:18:32 13 A. I don't know.

14:18:33 14 Q. Obviously one had to be used; right?

14:18:35 15 A. Yes.

14:18:35 16 Q. Okay.

14:18:36 17 A. It wasn't relevant for the purposes of just
14:18:40 18 becoming familiar with the Schlieren instruments.

14:18:44 19 Q. So would you -- would you agree with me that
14:18:47 20 the 2009-2010 Schlieren imaging done wasn't really an
14:18:52 21 internal testing that was done on whether or not the
14:18:56 22 Bair Hugger device disrupts the sterile surgical
14:19:01 23 field?

14:19:01 24 A. Yes. It was not a formal test.

14:19:03 25 Q. Okay. And therefore, since it wasn't a

14:19:06 1 formal test, there is no report.

14:19:08 2 A. That's correct.

14:19:09 3 Q. Because all formal tests, you have a report
14:19:15 4 at Arizant and 3M; correct?

14:19:16 5 MR. BLACKWELL: Object to the form of the
14:19:17 6 question as beyond the scope of the 30(b)(6)
14:19:19 7 designations.

14:19:20 8 A. Every formal test has a report --

9 Q. Okay.

14:19:22 10 A. -- or at least a designation that it was
14:19:23 11 conducted.

14:19:24 12 Q. So would you agree with me that the on --
14:19:26 13 only formal test performed with respect to the Bair
14:19:31 14 Hugger device disrupting the sterile surgical field
14:19:34 15 was the 2010-2011 Schlieren testing done at 3M?

14:19:37 16 A. Yes.

14:19:39 17 Q. Okay. But that's not exactly true; is it?

14:19:49 18 MR. BLACKWELL: I object to the question as
14:19:50 19 argumentative.

14:19:51 20 MR. ASSAAD: It is argumentative.

14:19:52 21 MR. BLACKWELL: Well I object.

14:19:53 22 MR. ASSAAD: All right.

14:19:53 23 A. Well I don't recall any other ones being
14:19:55 24 done.

14:19:55 25 Q. You actually did calculations in 1998 with

14:19:58 1 respect to whether or not the Bair Hugger device

14:20:00 2 disrupts the air coming out of its laminar flow and

14:20:05 3 whether or not it disrupts laminar flow; correct?

14:20:07 4 A. Right. But you asked me if we had done any

14:20:09 5 tests. Those are just calculations that I did.

14:20:11 6 Q. Okay. So you -- you'd distinguish between

14:20:15 7 internal testing whether -- like the physical test or

14:20:17 8 calculation?

14:20:17 9 A. Yes.

14:20:18 10 Q. Okay. The next is internal testing with

14:20:49 11 respect to dispersement of airborne particles and/or

14:20:54 12 pathogens. What internal testing has been done with

14:20:56 13 respect to -- by 3M or the company with respect to

14:20:59 14 dispersement of airborne particles and/or pathogens?

14:21:03 15 A. I'm not aware of any that has been done

14:21:06 16 internally.

14:21:06 17 Q. Okay. When you say you're not aware, is it

14:21:14 18 safe to say that 3M --

14:21:15 19 A. 3M was --

14:21:17 20 Q. -- or Arizant did not do any internal

14:21:18 21 testing with respect to the dispersement of airborne

14:21:22 22 particles and/or pathogens?

14:21:25 23 A. Yes.

14:21:26 24 Q. With respect to internal testing whether the

14:21:40 25 Bair Hugger device harbors bacteria inside the device,

14:21:43 1 was there any internal testing done by the company,
14:21:46 2 3M, Arizant, Augustine Medical?

14:21:48 3 A. No.

14:21:48 4 Q. Okay. With respect to the Bair Hugger
14:21:54 5 patient warming system causing surgical-site
14:21:57 6 infection, was there any internal testing done by the
14:22:01 7 company, 3M, Arizant or Augustine Medical, with
14:22:04 8 respect to that?

14:22:04 9 A. And what was the outcome?

14:22:07 10 Q. Surgical-site infection.

14:22:09 11 A. No.

14:22:10 12 Q. Going back to disruption -- disrupting the
14:22:34 13 sterile surgical field, 3M performed computational
14:22:38 14 fluid dynamics to determine that; correct?

14:22:40 15 A. Yes.

14:22:41 16 Q. Okay. Is that internal or external?

14:22:42 17 A. That was done externally.

14:22:44 18 Q. Okay. So there was no internal
14:22:47 19 computational fluid dynamics testing done with respect
14:22:50 20 to disrupting the -- the sterile surgical field;
14:22:56 21 correct?

14:22:56 22 A. That's correct.

14:22:57 23 Q. Okay.

14:22:58 24 A. Not internally.

14:22:59 25 Q. So with respect to subject area number six,

14:23:59 1 the only internal testing done by 3M is the Schlieren
14:24:05 2 imaging done in 2010-2011.

14:24:08 3 A. Yes.

14:24:09 4 Q. Topic number seven titled defendants'
14:24:36 5 knowledge and analysis of third-party testing
14:24:38 6 regarding the potential of the Bair Hugger patient
14:24:40 7 warming system, or any component thereof, to disrupt
14:24:43 8 the sterile surgical field, disperse airborne
14:24:48 9 particles and/or pathogens, harbor bacteria inside the
14:24:50 10 device, and/or cause surgical-site infection, are you
14:24:51 11 prepared to discuss this right now?

14:24:53 12 A. Yes.

14:24:53 13 Q. With respect to --

14:24:57 14 What I'd like to do is -- is go by one and
14:25:00 15 just to get the third-party testing, and we'll go back
14:25:03 16 later on. So with respect to sterile surgical field,
14:25:06 17 what third-party testing or knowledge do you have with
14:25:10 18 respect to the sterile -- surgical sterile field and
14:25:13 19 disrupting the surgical sterile field?

14:25:16 20 A. Well there was testing done by LUWA, a
14:25:25 21 company that certifies laminar airflow rooms in
14:25:29 22 Europe, that looked at the effect of the Bair Hugger
14:25:35 23 in a laminar airflow setting during a certification
14:25:39 24 process.

14:25:40 25 Q. That would be Sessler's article; correct?

14:25:42 1 A. Yes.

14:25:43 2 Q. Okay.

14:25:43 3 A. Yeah.

14:25:44 4 Q. Were any -- any other --

14:25:46 5 Any other third-party testing that you're

14:25:48 6 aware of with respect to disrupting the sterile

14:25:51 7 surgical field?

14:25:52 8 A. That we conducted? I -- I don't believe so.

14:26:00 9 Q. Well it says defendants' knowledge and

14:26:03 10 analysis of third-party testing.

14:26:04 11 A. I beg your pardon?

14:26:05 12 Q. Of third --

14:26:07 13 It says defendants' knowledge and analysis

14:26:09 14 of third-party testing, not what you just conducted.

14:26:12 15 A. Well we certainly analyzed a large number of

14:26:16 16 third-party clinical papers regarding this topic.

14:26:19 17 Q. Such as? Can you list them all?

14:26:21 18 A. Well I mean, from memory, probably not all

14:26:24 19 of them, but things like Huang and Moretti, Avidan,

14:26:33 20 there was a recent paper by Kimberger, and we

14:26:47 21 certainly analyzed the papers by McGovern and Reed and

14:26:51 22 Albrecht. And, you know, a large -- large number of

14:27:01 23 papers like -- like those.

14:27:02 24 Q. What else?

14:27:03 25 A. You know, right now I -- I -- I cannot

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14:27:11 1 remember the -- any other --

14:27:13 2 Q. Legg?

14:27:13 3 A. Legg, yeah.

14:27:15 4 Q. Anything else?

14:27:18 5 A. [REDACTED]

14:27:24 6 [REDACTED]

14:27:30 7 [REDACTED]

14:27:30 8 [REDACTED] [REDACTED] [REDACTED]

14:27:32 9 [REDACTED] [REDACTED]

10 [REDACTED] [REDACTED]

14:27:34 11 [REDACTED] [REDACTED]

14:27:34 12 [REDACTED] [REDACTED]

14:27:35 13 [REDACTED] [REDACTED]

14:27:38 14 [REDACTED] [REDACTED]

14:27:40 15 [REDACTED] [REDACTED]

14:27:41 16 [REDACTED] [REDACTED]

14:27:43 17 [REDACTED] [REDACTED]

14:27:47 18 [REDACTED]

14:27:50 19 [REDACTED]

14:27:54 20 [REDACTED] [REDACTED]

21 [REDACTED]

14:27:57 22 [REDACTED] [REDACTED]

23 [REDACTED]

14:27:58 24 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

14:28:00 25 [REDACTED] [REDACTED]

			187
14:28:05	1	A.	[REDACTED]
14:28:09	2		[REDACTED]
14:28:16	3		[REDACTED]
14:28:23	4	[REDACTED]	[REDACTED] [REDACTED]
14:28:26	5		[REDACTED]
14:28:27	6	[REDACTED]	[REDACTED]
14:28:31	7	[REDACTED]	[REDACTED]
14:28:33	8		[REDACTED]
14:28:34	9	[REDACTED] [REDACTED]	[REDACTED]
14:28:36	10	[REDACTED] [REDACTED]	[REDACTED]
14:28:37	11		[REDACTED]
14:28:38	12	[REDACTED]	[REDACTED]
14:28:39	13	[REDACTED]	[REDACTED]
14:28:40	14		[REDACTED]
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14:28:49	16		[REDACTED]
14:28:53	17	[REDACTED]	[REDACTED]
14:28:54	18	[REDACTED]	[REDACTED]
14:29:04	19	[REDACTED]	[REDACTED]
14:29:06	20	[REDACTED]	[REDACTED]
14:29:06	21	[REDACTED] [REDACTED]	[REDACTED]
14:29:09	22	[REDACTED]	[REDACTED]
14:29:10	23	[REDACTED]	[REDACTED]
14:29:13	24	[REDACTED] [REDACTED]	[REDACTED]
14:29:16	25		[REDACTED]

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14:29:18	1	Q.	[REDACTED]
14:29:20	2	[REDACTED]	[REDACTED]
14:29:20	3	[REDACTED]	[REDACTED]
14:29:23	4	[REDACTED]	
14:29:23	5	[REDACTED]	[REDACTED]
14:29:24	6	[REDACTED]	[REDACTED]
14:29:27	7	[REDACTED]	[REDACTED]
14:29:29	8	[REDACTED]	
14:29:29	9	[REDACTED]	[REDACTED]
14:29:30	10	[REDACTED]	[REDACTED]
14:29:34	11	[REDACTED]	
14:29:36	12	[REDACTED]	[REDACTED]
14:29:38	13	[REDACTED]	[REDACTED]
14:29:40	14	[REDACTED]	
14:29:41	15	[REDACTED]	[REDACTED]
14:29:42	16	[REDACTED]	[REDACTED]
14:29:52	17		[REDACTED]
14:29:54	18	[REDACTED]	[REDACTED]
14:29:57	19	[REDACTED]	
14:29:59	20	[REDACTED]	[REDACTED]
14:30:01	21		[REDACTED] [REDACTED]
14:30:03	22	[REDACTED]	
14:30:04	23	[REDACTED]	[REDACTED]
14:30:07	24	[REDACTED]	[REDACTED]
14:30:11	25	[REDACTED]	[REDACTED]

			189
14:30:15	1	[REDACTED]	
14:30:18	2	[REDACTED] [REDACTED]	
14:30:20	3	[REDACTED] [REDACTED]	
14:30:24	4	[REDACTED]	
14:30:31	5	[REDACTED]	
14:30:35	6	[REDACTED] [REDACTED] [REDACTED]	
14:30:39	7	[REDACTED] [REDACTED]	
14:30:40	8	[REDACTED] [REDACTED]	
14:30:41	9	[REDACTED] [REDACTED]	
14:30:43	10	[REDACTED] [REDACTED]	
14:30:55	11	[REDACTED]	
14:30:58	12	[REDACTED]	
14:30:59	13	[REDACTED] [REDACTED] [REDACTED]	
14:31:02	14	[REDACTED]	
14:31:05	15	[REDACTED] [REDACTED] [REDACTED]	
14:31:11	16	[REDACTED]	
14:31:11	17	[REDACTED] [REDACTED]	
14:31:13	18	[REDACTED] [REDACTED] [REDACTED]	
14:31:15	19	[REDACTED]	
14:31:17	20	[REDACTED] [REDACTED]	
14:31:18	21	[REDACTED] [REDACTED]	
14:31:19	22	[REDACTED] [REDACTED]	
14:31:22	23	[REDACTED]	
14:31:25	24	[REDACTED]	
14:31:30	25	[REDACTED]	

				190
14:31:31	1	Q.	[REDACTED]	[REDACTED]
14:31:42	2		[REDACTED]	[REDACTED]
14:31:45	3		[REDACTED]	
14:31:45	4		[REDACTED]	[REDACTED]
14:31:46	5		[REDACTED]	[REDACTED]
14:31:47	6		[REDACTED]	[REDACTED]
14:31:50	7		[REDACTED]	
14:31:51	8		[REDACTED]	[REDACTED]
14:31:51	9		[REDACTED]	[REDACTED]
14:31:56	10		[REDACTED]	[REDACTED]
14:31:58	11		[REDACTED]	[REDACTED]
14:32:01	12		[REDACTED]	[REDACTED]
14:32:16	13		[REDACTED]	[REDACTED]
14:32:18	14		[REDACTED]	[REDACTED]
14:32:23	15		[REDACTED]	[REDACTED]
14:32:26	16		[REDACTED]	
14:32:27	17		[REDACTED]	[REDACTED]
14:32:37	18		[REDACTED]	[REDACTED]
14:32:38	19		[REDACTED]	[REDACTED]
14:32:39	20		[REDACTED]	[REDACTED]
14:32:40	21		[REDACTED]	[REDACTED]
14:32:45	22		[REDACTED]	[REDACTED]
14:32:46	23		[REDACTED]	[REDACTED]
14:32:50	24		[REDACTED]	[REDACTED]
14:32:58	25		[REDACTED]	[REDACTED]

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14:33:00	1	[REDACTED]	
14:33:02	2	[REDACTED]	
14:33:03	3	[REDACTED]	
14:33:06	4	[REDACTED]	
14:33:08	5	[REDACTED]	
14:33:16	6	[REDACTED]	
14:33:21	7	[REDACTED]	
14:33:27	8	[REDACTED]	
14:33:31	9	[REDACTED]	
14:33:36	10	[REDACTED]	
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14:35:06	20	[REDACTED]	
14:35:08	21	[REDACTED]	
14:35:11	22	[REDACTED]	
14:35:16	23	[REDACTED]	
14:35:16	24	[REDACTED]	
14:35:18	25	[REDACTED]	

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14:35:20	1	Q.	[REDACTED]
14:35:24	2	[REDACTED]	[REDACTED]
14:35:26	3	[REDACTED]	
14:35:26	4	[REDACTED]	[REDACTED]
14:35:29	5	[REDACTED]	[REDACTED]
14:35:33	6	[REDACTED]	
14:35:34	7	[REDACTED]	[REDACTED]
14:35:38	8	[REDACTED]	[REDACTED]
14:35:42	9	[REDACTED]	[REDACTED]
14:35:46	10	[REDACTED]	
14:35:46	11		[REDACTED] [REDACTED]
14:35:47	12	[REDACTED]	
14:35:48	13	[REDACTED]	[REDACTED]
14:35:50	14	[REDACTED]	[REDACTED]
14:35:53	15	[REDACTED]	[REDACTED]
14:35:56	16	[REDACTED]	
14:35:57	17	[REDACTED]	[REDACTED]
14:35:59	18	[REDACTED]	
14:36:00	19	[REDACTED]	[REDACTED]
14:36:03	20	[REDACTED]	[REDACTED]
14:36:06	21	[REDACTED]	
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14:36:12	23	[REDACTED]	
14:36:13	24	[REDACTED]	[REDACTED]
14:36:14	25	[REDACTED]	[REDACTED]

			193
14:36:20	1	[REDACTED]	
14:36:23	2	[REDACTED]	
14:36:26	3	[REDACTED] [REDACTED]	
14:36:27	4	[REDACTED]	
14:36:27	5	[REDACTED] [REDACTED]	
14:36:29	6	[REDACTED]	
14:36:32	7	[REDACTED]	
14:36:33	8	[REDACTED] [REDACTED]	
14:36:36	9	[REDACTED]	
14:36:40	10	[REDACTED]	
14:36:51	11	[REDACTED]	
14:36:56	12	[REDACTED] [REDACTED]	
14:36:57	13	[REDACTED]	
14:37:00	14	[REDACTED] [REDACTED]	
14:37:02	15	[REDACTED] [REDACTED]	
14:37:02	16	[REDACTED] [REDACTED]	
14:37:04	17	[REDACTED] [REDACTED]	
14:37:05	18	[REDACTED]	
14:37:05	19	[REDACTED] [REDACTED]	
14:37:07	20	[REDACTED] [REDACTED] [REDACTED]	
14:37:08	21	[REDACTED]	
14:37:10	22	[REDACTED] [REDACTED]	
14:37:10	23	[REDACTED] [REDACTED]	
14:37:11	24	[REDACTED] [REDACTED]	
14:37:13	25	[REDACTED]	

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14:37:15	1	[REDACTED]	[REDACTED]
14:37:15	2	[REDACTED]	[REDACTED]
14:37:15	3	[REDACTED]	
14:37:15	4	[REDACTED]	[REDACTED]
14:37:15	5	[REDACTED]	[REDACTED]
14:37:17	6	[REDACTED]	[REDACTED]
14:37:20	7	[REDACTED]	[REDACTED]
14:37:22	8	[REDACTED]	
14:37:24	9	[REDACTED]	
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14:37:30	11	[REDACTED]	[REDACTED]
14:37:32	12	[REDACTED]	[REDACTED]
14:37:34	13	[REDACTED]	[REDACTED]
14:37:42	14	[REDACTED]	
14:37:47	15	[REDACTED]	
14:37:49	16	[REDACTED]	
14:37:54	17	[REDACTED]	
14:37:57	18	[REDACTED]	
14:37:59	19	[REDACTED]	[REDACTED]
14:38:01	20	[REDACTED]	
14:38:03	21	[REDACTED]	
14:38:07	22	[REDACTED]	
14:38:12	23	[REDACTED]	
14:38:16	24	[REDACTED]	[REDACTED]
14:38:17	25	[REDACTED]	[REDACTED]

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14:38:18	1	[REDACTED]
14:38:19	2	[REDACTED]
14:38:22	3	[REDACTED]
14:38:23	4	[REDACTED]
14:38:25	5	[REDACTED]
14:38:30	6	[REDACTED]
14:38:32	7	[REDACTED]
14:38:34	8	[REDACTED]
14:38:37	9	[REDACTED]
14:38:40	10	[REDACTED]
14:38:40	11	[REDACTED]
14:38:42	12	[REDACTED]
14:38:55	13	[REDACTED]
14:38:58	14	[REDACTED]
14:38:59	15	[REDACTED]
14:39:04	16	[REDACTED]
14:39:06	17	[REDACTED]
14:39:10	18	[REDACTED]
14:39:13	19	[REDACTED]
14:39:17	20	[REDACTED]
14:39:21	21	[REDACTED]
14:39:22	22	[REDACTED]
14:39:30	23	[REDACTED]
14:39:33	24	[REDACTED]
14:39:37	25	[REDACTED]

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14:39:42	1	[REDACTED]
14:39:43	2	[REDACTED]
14:39:46	3	[REDACTED]
14:39:49	4	[REDACTED]
14:39:52	5	[REDACTED]
14:39:55	6	[REDACTED]
14:40:01	7	[REDACTED]
14:40:01	8	[REDACTED]
14:40:06	9	[REDACTED]
14:40:10	10	[REDACTED]
14:40:12	11	[REDACTED]
14:40:14	12	[REDACTED]
14:40:16	13	[REDACTED]
14:40:18	14	[REDACTED]
14:40:19	15	[REDACTED]
14:40:20	16	[REDACTED]
14:40:22	17	[REDACTED]
14:40:22	18	[REDACTED]
14:40:23	19	[REDACTED]
14:40:26	20	[REDACTED]
14:40:29	21	[REDACTED]
14:40:31	22	[REDACTED]
14:40:34	23	[REDACTED]
14:40:36	24	[REDACTED]
14:41:05	25	[REDACTED]

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14:41:07	1	[REDACTED]
14:41:07	2	[REDACTED]
14:41:13	3	[REDACTED]
14:41:16	4	[REDACTED]
14:41:17	5	[REDACTED]
14:41:21	6	[REDACTED]
14:41:21	7	[REDACTED]
14:41:22	8	[REDACTED]
14:41:23	9	[REDACTED]
14:41:24	10	[REDACTED]
	11	[REDACTED]
14:41:28	12	[REDACTED]
14:41:28	13	[REDACTED]
14:41:31	14	[REDACTED]
14:41:31	15	[REDACTED]
14:41:31	16	[REDACTED]
14:41:33	17	[REDACTED]
14:41:34	18	[REDACTED]
14:41:34	19	[REDACTED]
14:41:35	20	[REDACTED]
14:41:37	21	[REDACTED]
14:41:39	22	[REDACTED]
14:41:42	23	[REDACTED]
14:41:42	24	[REDACTED]
14:41:43	25	[REDACTED]

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Q. Okay. So Sessler, Moretti, Huang, Avidan, Kimberger, McGovern, Reed, Albrecht, Legg are all articles with respect that you have knowledge and then analyzed regarding disruption of the sterile field.

When I say "you," I mean 3M.

A. Yes.

Q. Any other articles?

A. I'm sure there are others, but I -- I can't remember them right now.

Q. Well, you were supposed to remember them right now because I'm taking a 30(b)(6) deposition of the company's corporate knowledge.

MR. BLACKWELL: I object, move to strike as to what he's supposed to be. Remember, a 30(b)(6) deposition is not a memory test. So I disagree with it and --

Q. What --

14:42:49 1 MR. BLACKWELL: -- and you can disregard
14:42:50 2 counsel's comments in that regard.

14:42:53 3 You may ask your question, Mr. Assaad.

14:42:55 4 Q. What is defendant --

14:42:58 5 Sitting here today, what is defendants'

14:43:01 6 knowledge and analysis of third-party testing

14:43:04 7 regarding the potential of the Bair Hugger patient

14:43:06 8 warming system, or any component therefore, to --

14:43:10 9 thereof, to disrupt the sterile surgical field,

14:43:13 10 besides articles that I've listed?

14:43:19 11 A. Well I -- I mean I think that's the majority

14:43:22 12 of the articles that I'm aware of. Again, there may

14:43:24 13 be one or two that I'm not remembering, but I believe

14:43:28 14 that's it.

14:43:29 15 Q. Okay. And Sessler was funded by 3M;

14:43:35 16 correct?

14:43:35 17 A. Well LUWA was -- the company that conducted

14:43:40 18 the study was -- was paid by -- by Arizant.

14:43:44 19 Q. Okay. So the Sessler article, which is a

14:43:55 20 third-party testing which was funded by Arizant;

14:44:01 21 correct?

14:44:01 22 A. Yes.

14:44:02 23 Q. Okay.

14:44:02 24 A. I believe that is disclosed in that article.

14:44:05 25 Q. Yeah. And Moretti, was that funded by

14:44:09 1 Arizant?

14:44:10 2 A. No.

14:44:10 3 Q. How about Huang, funded by Arizant or

14:44:15 4 Augustine Medical?

14:44:16 5 A. No.

14:44:25 6 Q. Was Sessler or Moretti analyzed by 3M?

14:44:38 7 A. Moretti was.

14:44:41 8 I'm not sure what you mean by "analyzed."

14:44:45 9 You mean the paper or the --

14:44:46 10 Q. Well, for example, 3M put out and you put

14:44:51 11 out documentation regarding the anal -- analysis of

14:44:55 12 the McGovern paper; correct?

14:44:56 13 A. Yes.

14:44:57 14 Q. So 3M analyzed that, formally analyzed it

14:45:00 15 and published an analysis on the McGovern paper;

14:45:03 16 correct?

14:45:03 17 A. I don't think we published anything. We --

14:45:06 18 Q. Published to customers. I didn't mean

14:45:08 19 published as in published in the literature.

14:45:10 20 A. I'm not sure we actually published that to

14:45:14 21 customers. I think we had a lot of internal --

22 Q. Okay.

14:45:14 23 A. -- documents discussing our analysis of that

14:45:16 24 paper -- of those papers.

14:45:17 25 Q. Okay. Was there any internal documents

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14:45:19 1 discussing your analysis of the Moretti paper?

14:45:21 2 A. I'm -- I'm certain I must have sent e-mails
14:45:27 3 around discussing that paper.

14:45:28 4 Q. Okay. With respect to Moretti --

14:45:36 5 Let's start off with the first one, Sessler.
14:45:39 6 Do you agree with me, in the Sessler study that was
14:45:42 7 done by LUWA, that when the forced-air warming was on,
14:45:46 8 there were more particles over the surgical site?

14:45:49 9 MR. BLACKWELL: I object to the form of the
14:45:50 10 question.

14:45:50 11 A. Well in -- in one case.

14:45:51 12 Q. Well the averages were mostly above --

14:45:53 13 The average particles over the surgical site
14:45:55 14 were always greater for the forced-air warming -- for
14:45:58 15 the forced-air warming on than when it was off.

14:46:00 16 MR. BLACKWELL: Same objection.

14:46:01 17 A. In -- yeah. In one case when it was on,
14:46:07 18 yes.

14:46:07 19 Q. Just one case?

14:46:09 20 A. I believe it's just in one case.

14:46:11 21 But you have to remember, that study is not
14:46:12 22 a study that looks at the particulates being ejected
14:46:16 23 by the warming unit, it's a study that looks at the
14:46:19 24 ability of the laminar airflow system to reduce the
14:46:24 25 particulate load that comes from an external source

14:46:28 1 while the forced-air warming unit is being operated.

14:46:30 2 Q. It's there to check the protective effect of
14:46:33 3 the laminar flow system.

14:46:35 4 A. That -- that's right.

14:46:35 5 Q. Correct?

14:46:36 6 A. But the -- but the particulates are
14:46:37 7 generated externally from the warming unit. They're
14:46:42 8 not being ejected from the warming unit, they're being
14:46:45 9 in -- introduced --

14:46:46 10 Q. I -- I never said they're being ejected from
14:46:48 11 the warming unit.

14:46:49 12 MR. BLACKWELL: You may finish your answer.

14:46:50 13 A. But I'm -- but I'm explaining the
14:46:52 14 difference between --

14:46:52 15 Q. Okay.

14:46:53 16 A. -- a -- a study where you're looking at
14:46:55 17 particulates that emanate from the warming unit as
14:46:57 18 opposed to a study where the particulates were placed
14:47:00 19 within the room to check the protective effect of the
14:47:04 20 laminar airflow.

14:47:06 21 Q. Well I agree with you that the study that is
14:47:09 22 the standard that's used for the -- for the Sessler
14:47:12 23 article, which is a DIN standard, is not -- is not
14:47:17 24 used to count particles. Correct?

14:47:19 25 A. I'm not sure what you mean by that exactly.

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14:47:25 1 Q. It's -- it's to determine whether or not --
14:47:28 2 The standard that was used in that study is
14:47:30 3 to determine whether or not the operating room theater
14:47:33 4 complies with a DIN standard; correct?

14:47:35 5 A. Well it --
14:47:37 6 The laminar airflow system within the
14:47:39 7 operating room, yes.

14:47:40 8 Q. Whether it -- and -- strike that.

14:47:43 9 And to comply with the DIN standard in that
14:47:46 10 Sessler article, you just have to have a protective
14:47:55 11 effect of two; correct?

12 THE REPORTER: I'm sorry --

13 MR. BLACKWELL: I object to the form of the
14 question.

15 Q. To have --

16 To comply with the DIN standard, D-I-N, you
14:47:56 17 have to have a protective effect of two.

14:47:56 18 A. Yes.

14:47:56 19 Q. Okay. That standard was not created to
14:48:01 20 compare different modes of patient warming.

14:48:07 21 A. Well in fact there are no standards for
14:48:09 22 that.

14:48:09 23 Q. Okay. But that was the purpose of the study
14:48:11 24 that you, 3M, funded, was to compare the particle
14:48:18 25 count above the surgical site between forced-air

14:48:24 1 warming and conductive warming.

14:48:26 2 A. Forced-air warming and no warming I believe.

14:48:28 3 Q. And no warming, correct. I'm sorry.

14:48:30 4 Correct?

14:48:30 5 A. Yes.

14:48:31 6 Q. Okay. But the DIN standard was not created

14:48:35 7 to perform that type of test; correct?

14:48:37 8 A. Well that's not its main purpose, no.

14:48:47 9 Q. It's not even its secondary, tertiary,

14:48:51 10 whatever purpose. There's nothing in the DIN standard

14:48:52 11 that -- that exists that says you could also use the

14:48:55 12 standard to calculate particle counts when forced-air

14:48:58 13 warming is used.

14:48:59 14 A. That's correct.

14:48:59 15 Q. Okay. Now with the Moretti study, which

16 was --

14:49:22 17 Are you familiar with the Moretti study that

14:49:23 18 you cited that was --

14:49:23 19 A. I am.

14:49:24 20 Q. Do you know what Bair Hugger unit was used

14:49:26 21 in that study?

14:49:27 22 A. I believe it was a 505E.

14:49:31 23 Q. And the 505E has less flow than the 505;

14:49:34 24 correct?

14:49:34 25 A. Yes.

14:49:35 1 Q. Because the Europeans complained about noise
14:49:39 2 too much. One of the reasons.

14:49:39 3 A. No.

14:49:40 4 Q. That's not one --

14:49:42 5 What's the reason then?

14:49:43 6 A. The reason is that the motor that's used in
14:49:47 7 the 505 is an induction motor and its speed is
14:49:49 8 proportional to the line frequency, and in Europe, or
14:49:52 9 at least in Italy, the line frequency is 50 hertz as
14:49:57 10 opposed to 60 hertz in the United States.

14:49:58 11 Q. And was 3M or Arizant or the company
14:50:00 12 involved in any way with the Moretti study?

14:50:02 13 A. No. Only after I did contact Dr. Moretti to
14:50:08 14 ask him some questions, but this is after the study
14:50:10 15 was published.

14:50:11 16 Q. And that wasn't done in a laminar flow;
14:50:14 17 correct? That was --

14:50:14 18 A. That was done in a conventionally ventilated
14:50:19 19 operating room.

14:50:20 20 Q. Well when you say conventional, is it
21 unidirectional?

22 A. Well I -- I mean conventional --

14:50:23 23 Q. Or don't you know?

14:50:25 24 A. Well conventionally ventilated, that's all I
14:50:27 25 know.

14:50:27 1 Q. Okay. So you don't know if it was
14:50:29 2 unidirectional or, you know, the air going from top to
14:50:31 3 bottom or left to right or anything like that.
14:50:34 4 A. Well both of those would be unidirectional.
14:50:37 5 Q. But you don't know which unidirectional, if
14:50:39 6 it was.
14:50:39 7 A. I don't know.
14:50:40 8 Q. Okay. You agree with me that the Moretti
14:51:01 9 study has many flaws; correct?
14:51:03 10 MR. BLACKWELL: I object to the form of the
14:51:04 11 question.
14:51:05 12 A. Well I mean what flaws?
14:51:09 13 Q. Well you -- you analyzed Moretti; correct?
14:51:13 14 A. I did.
14:51:13 15 Q. Okay. Do you agree with me that Moretti
14:51:15 16 consists of certain flaws?
14:51:17 17 A. Well if you have my paper, I'd be happy to
14:51:21 18 comment on my analysis.
14:51:21 19 Q. Well I'm asking what -- what your knowledge
14:51:22 20 is today, 3M's knowledge today. Are you aware --
14:51:25 21 Are you saying there are no flaws in the
14:51:26 22 Moretti article or study?
14:51:28 23 A. Well every study has flaws.
14:51:33 24 Q. So you would agree with me that Moretti has
14:51:36 25 some flaws.

14:51:36 1 A. It may have some flaws.

14:51:38 2 Q. "Yes" or "no." Do you agree with me that
14:51:40 3 Moretti has flaws?

14:51:41 4 MR. BLACKWELL: I object as asked and
14:51:42 5 answered.

14:51:42 6 MR. ASSAAD: He has not answered the
14:51:44 7 question.

14:51:44 8 MR. BLACKWELL: You've answered the
14:51:46 9 question.

14:51:46 10 A. Well I mean you're not asking me
14:51:47 11 specifically --

14:51:47 12 Q. It's a simple "yes" or "no" question, sir.
14:51:47 13 Does the Moretti article have flaws? "Yes" or "no."
14:51:51 14 And if you say no, then we move on; if you say yes,
14:51:55 15 we'll discuss the flaws.

14:51:55 16 MR. BLACKWELL: Hang -- hang on one second.
14:51:56 17 This -- this colloquy has become talking over each
14:51:58 18 other, so if you could wait until he finishes his
14:52:00 19 question before you answer, and if you could wait
14:52:02 20 until he finishes his answer before you ask another
14:52:04 21 one, the court reporter would appreciate it and -- and
14:52:08 22 it makes a better record.

14:52:09 23 MR. ASSAAD: Thank -- thank you, Jerry.

14:52:10 24 Q. So do you understand my last question?

14:52:11 25 A. Yes, I understand your question.

14:52:12 1 Q. Does the Moretti article have flaws?

14:52:15 2 A. Well, a flaw that -- if -- if there is one
14:52:19 3 in the Moretti study, would be that it's relatively
14:52:22 4 small.

14:52:22 5 Q. Okay. So the sample size is small.

14:52:23 6 A. Yes.

14:52:24 7 Q. Okay. Would you agree another flaw is that
14:52:31 8 it was not randomized?

14:52:33 9 A. Yes.

14:52:33 10 Q. Based on the Moretti study, are you familiar
14:52:38 11 with when, at what time, they took samples regarding
14:52:42 12 bacterial count?

14:52:43 13 A. I don't recall exactly when that was done in
14:52:47 14 that study.

14:52:48 15 Q. Would that have an effect on when the sample
14:53:00 16 counts were taken with respect to whether or not the
14:53:04 17 study is accurate?

14:53:08 18 A. Well it might.

14:53:13 19 Q. You're aware that, according to Moretti's
14:53:28 20 study, the first sample was taken immediately after
14:53:33 21 placing the patient on the operating room table.

14:53:35 22 A. I believe that's correct, yes.

14:53:37 23 Q. Okay. And that's at a time when there's a
14:53:39 24 lot of movement around the operating room table and
14:53:43 25 that's most likely when you get your highest counts of

14:53:45 1 bacteria.

14:53:47 2 A. I think that's reasonable.

14:53:49 3 Q. Okay. And there was only 20 --

14:53:53 4 The sample size was only 20 people; correct?

14:53:55 5 A. Yes.

14:53:56 6 Q. Okay. Which, with infection rates being,

14:54:00 7 you know, one to three percent, that is a very

14:54:04 8 underpowered study with respect to surgical-site

14:54:08 9 infection.

14:54:09 10 MR. BLACKWELL: Object to the form of the

14:54:10 11 question.

14:54:10 12 A. If I recall, the -- the study wasn't powered

14:54:14 13 to look at surgical-site infection, it was powered to

14:54:17 14 look at the relative difference in numbers of colony-

14:54:23 15 forming units.

14:54:23 16 Q. Okay. And you agree that many of the

14:54:27 17 samples were taken regarding -- like the swab samples

14:54:30 18 of -- of -- before the skin was disinfected and the

14:54:34 19 surgical site was prepared.

14:54:36 20 A. Initially.

14:54:37 21 Q. Okay. And you agree with me another flaw of

14:54:41 22 the Moretti study is that they took the mean bacterial

14:54:46 23 load counts when the Bair Hugger was used and there's

14:54:50 24 no indication of at what times they actually did the

14:54:53 25 samples.

14:54:55 1 A. As I recall, there was the --

14:54:57 2 The time of extraction was not indicated.

14:55:05 3 Q. And because the study was underpowered, that
14:55:18 4 they could not get statistically significant results
14:55:20 5 with two of the three sample sites.

14:55:24 6 A. Well I -- I don't --

14:55:25 7 MR. BLACKWELL: I object to -- I object to
14:55:26 8 the form of the question.

14:55:27 9 A. I -- I don't know that it's underpowered to
14:55:30 10 detect differences in colony-forming units. It may be
14:55:33 11 under -- it's certainly underpowered to detect
14:55:36 12 differences in actual infection rates.

14:55:39 13 Q. According to the study, it states, "In any
14:55:41 14 case, in two of the sampling points (A2 and A3) no
14:55:45 15 significant differences (p-value greater than .05)
14:55:48 16 were observed between the two increases."

14:55:51 17 A. That doesn't necessarily --

14:55:52 18 MR. BLACKWELL: I -- I object to the form of
14:55:53 19 the question. There's no question pending. He's just
14:55:56 20 simply read a statement to you.

14:55:56 21 MR. ASSAAD: Are you going to keep on
14:55:57 22 coaching the witness?

14:55:58 23 MR. BLACKWELL: Are you going to ask a
14:55:59 24 question?

14:55:59 25 MR. ASSAAD: Well if you let me ask a

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14:56:01 1 question, but --

14:56:01 2 MR. BLACKWELL: Well if you would ask a
14:56:03 3 question, put it to him, but you sit here reading off
14:56:05 4 of a thing he doesn't have in front of him. If you
5 want to ask him a question about it, go ahead.

6 MR. ASSAAD: I'm just asking if he's
7 familiar with the document, Jerry.

14:56:09 8 MR. BLACKWELL: I mean you're just starting
14:56:09 9 now to simply talk into the air with a question
14:56:10 10 ending --

14:56:10 11 MR. ASSAAD: Mr. Blackwell -- Mr. Blackwell,
14:56:12 12 if you want to coach, you can coach all you want.

13 MR. BLACKWELL: I'm going to make my
14 statement for the record and -- and so --

15 MR. ASSAAD: I don't care if you want to
16 coach him --

17 MR. BLACKWELL: -- if you want to ask him a
18 question --

14:56:15 19 THE REPORTER: Okay. Let's go off the
20 record.

14:56:17 21 (Discussion off the record.)

14:56:47 22 BY MR. ASSAAD:

14:56:48 23 Q. You agree with me that, according to the
14:56:50 24 Moretti study, two of the sampling points, A2 and A3,
14:56:55 25 showed no significant differences in the CFU units

14:56:59 1 between Bair Hugger on and Bair Hugger off.

14:57:01 2 A. Yes. But you asked me if the study was

14:57:03 3 underpowered. P-value less than .05 does not

14:57:06 4 immediately mean that the study is underpowered, it

14:57:09 5 just means that the difference between the two means

14:57:12 6 was not statistically significant.

14:57:13 7 Q. And just to correct you, you meant p-value

14:57:16 8 over .05, not under.

14:57:18 9 A. Yes.

14:57:18 10 Q. Correct?

14:57:19 11 A. Yes.

14:57:19 12 Q. Okay. And defendants rely on Moretti with

14:57:51 13 respect -- with respect to whether or not the Bair

14:57:53 14 Hugger warming unit disrupts the sterile surgical

14:57:56 15 field; correct?

14:57:57 16 A. What do you mean "rely on?"

14:58:02 17 Q. Well when I said your knowledge and analysis

14:58:04 18 of third-party testing regarding the Bair Hugger

14:58:08 19 causing disruption of the sterile field, that's one of

14:58:12 20 the stuff -- cites -- articles that you rely upon in

14:58:14 21 using.

14:58:14 22 A. It's one of the pieces of evidence, yes.

14:58:16 23 Q. Okay.

14:58:17 24 A. It's not the only one.

14:58:19 25 Q. And you agree with me that Moretti is

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14:58:21 1 inconclusive as to whether or not the Bair Hugger unit
14:58:25 2 750 disrupts the sterile surgical field.

14:58:31 3 A. Well the 750 wasn't used in that study.

14:58:33 4 Q. Neither was the 505; correct?

14:58:36 5 A. No, I think it was the 505 in that study.

14:58:38 6 Q. 505E.

14:58:39 7 A. Well 505E, yes.

14:58:41 8 Q. Which has lower airflow than the 505.

14:58:45 9 A. Yes.

14:58:45 10 Q. Okay. And the 505E is not used in the
14:58:46 11 United States.

14:58:47 12 A. No, it is not.

14:58:49 13 Q. Okay. With respect to surgical site --
14:59:15 14 disruption of the -- of the sterile field, you do not
14:59:18 15 mention any CFD analysis. Did 3M do a CFD analysis,
14:59:24 16 third party?

14:59:24 17 A. Yes.

14:59:25 18 Q. Okay. Would that fall under this category
14:59:26 19 as well?

14:59:27 20 A. Well it's -- it's not a test, it's a -- it's
14:59:29 21 a computational analysis.

14:59:32 22 Q. Okay. Well I take testing and analysis and
14:59:37 23 calculations as all being tests in some way or other,
14:59:41 24 whether a physical test or a calculation test. Is
14:59:45 25 that fair? Is that the definition of testing?

14:59:51 1 A. Well I --

14:59:52 2 In a laboratory we normally think of a test
14:59:54 3 as a situation where quantitative data is measured in
15:00:03 4 response to some activity, and -- and then an analysis
15:00:06 5 is performed.

15:00:17 6 Q. Well with respect to the computational fluid
15:00:21 7 dynamics, who is the -- who is the third-party entity
15:00:32 8 that performed that type of analysis?

15:00:35 9 A. Well I believe there have been a couple of
15:00:37 10 them. Farud Memarzadeh conducted one.

15:00:45 11 Q. Farhad Memarzadeh?

15:00:48 12 A. Yeah.

15:00:49 13 Q. Okay.

15:00:49 14 A. And Professor Abraham at the University of
15:00:53 15 St. Thomas conducted one.

15:00:55 16 Q. Anyone else?

15:00:56 17 A. I believe that's all.

15:00:59 18 Q. And when did Abraham conduct his CFD
15:01:04 19 analysis?

15:01:04 20 A. In 2016.

15:01:08 21 Q. What about Farhad Memarzadeh?

15:01:12 22 A. I don't -- I don't remember the year that
15:01:14 23 that was done.

15:01:15 24 Q. Okay. And so those are the only two
15:01:21 25 analyses that 3M has any knowledge --

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15:01:24 1 Or there's only two CFD analyses that 3M has
15:01:29 2 knowledge of with respect to forced-air warming.
15:01:31 3 A. Yes.
15:01:34 4 Q. Okay. And the Farhad Memarzadeh, do you
15:01:38 5 know whether or not, when you analyzed it, he used the
15:01:40 6 505 or the 750?
15:01:42 7 A. I -- I don't believe any warming unit was
15:01:48 8 used to make that calculation.
15:01:52 9 Q. Well there has to be specifications with
15:01:56 10 respect to be able to do a computational fluid
15:01:59 11 dynamics; correct?
15:01:59 12 A. Yes.
15:02:00 13 Q. So what specifications did they use in
15:02:03 14 the -- did Farhad Memarzadeh use with respect to his
15:02:06 15 CFD analysis, if you know?
15:02:08 16 A. I don't know.
15:02:08 17 Q. Okay. What about Abraham?
15:02:10 18 A. He used data from the model 750 warming
15:02:14 19 unit.
15:02:17 20 Q. Okay. And is that something that you
15:02:22 21 worked --
15:02:23 22 Have you met Mr. Abraham?
15:02:24 23 A. Yes.
15:02:24 24 Q. Okay. Did you provide him that information?
15:02:27 25 A. I did not.

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15:02:27 1 Q. Okay. How is it that Abraham was hired to
15:02:34 2 do third-party testing of the -- by using a CFD
15:02:40 3 analysis?

15:02:40 4 A. He's a very-well-known heat-transfer expert
15:02:43 5 in Minneapolis -- or St. Paul.

15:02:45 6 Q. Was that someone that you located, or
15:02:48 7 somebody else?

15:02:49 8 A. I -- I knew of Professor Abraham, but I
15:02:52 9 think someone else located him.

15:02:53 10 Q. So how -- how did 3M obtain the services of
15:02:58 11 Mr. Abraham?

15:02:59 12 A. I -- I don't know how he was identified, but
15:03:05 13 he -- he worked under the direction of Dr. Issa, my
15:03:10 14 former boss.

15:03:21 15 Q. You said he was a well-known heat-transfer
15:03:24 16 expert. What's your basis behind that?

15:03:27 17 A. Well he was a T.A. when I took heat transfer
15:03:30 18 and thermodynamics, and then subsequently became a
15:03:32 19 professor at St. Thomas as a heat transfer, so I've
15:03:37 20 known him for some time.

15:03:42 21 Q. You agree with me that the Huang study has
15:03:52 22 flaws; correct?

15:03:52 23 A. All studies have flaws.

15:03:53 24 Q. But specifically the Huang study has flaws.

15:03:56 25 A. I suspect that it does.

15:03:57 1 Q. What are the flaws of the Huang study when
15:04:16 2 you analyzed it?

15:04:17 3 A. I don't have my data here in front of me,
15:04:20 4 but I'm sure that I've written extensively on that
15:04:24 5 study.

15:04:29 6 Q. Do you agree the sample size was small?

15:04:32 7 A. Yes, I believe the sample size was pretty
15:04:34 8 small in the Huang study.

15:04:36 9 Q. It was only 16 people; correct?

15:04:38 10 A. Yeah, I think so.

15:04:39 11 Q. It used the Bair Hugger 505; correct?

15:04:42 12 A. I believe that's the unit that was used.

15:04:43 13 Q. And that has less airflow than the 750;
15:04:47 14 correct?

15:04:47 15 A. Yes.

15:04:48 16 Q. And Huang even acknowledges, and I think you
15:04:54 17 acknowledged it in the Moretti study, that there's a
15:04:58 18 higher count of particles or bacteria in the beginning
15:05:00 19 of surgery in room air because of unrestricted
15:05:04 20 movement of personnel in and out of an operating room.

15:05:08 21 A. Yes.

15:05:09 22 Q. So taking a sample size of CFUs or particles
15:05:14 23 when you first lay down the patient is really not a
15:05:18 24 good indicator of particles or CFUs with respect to
15:05:27 25 what's really going on in an operating room during

15:05:29 1 surgery.

15:05:30 2 MR. BLACKWELL: Object to the form of the
15:05:31 3 question.

15:05:31 4 A. Well I don't know what the relationship is
15:05:34 5 between the initial particle load at the beginning of
15:05:38 6 surgery and later on.

15:05:41 7 Q. I agree. But before an incision is made,
15:05:44 8 usually things become more static than when the
15:05:46 9 patient is being placed and being prepped and people
15:05:49 10 are running around the operating room; correct?

15:05:51 11 MR. BLACKWELL: Object to the form of the
15:05:52 12 question.

15:05:52 13 A. In -- in theory, yes.

15:05:54 14 Q. Okay. And that's what Huang is saying here;
15:05:56 15 correct?

15:05:56 16 A. Yes.

15:05:56 17 Q. Okay. With respect to the forced-air
15:06:12 18 warming analysis or knowledge of disrupting the
15:06:15 19 sterile field, 3M has compared -- or indicated that
15:06:27 20 people moving around disrupts the sterile field;
15:06:34 21 correct?

15:06:34 22 A. One of many things --

15:06:35 23 Q. Okay.

15:06:36 24 A. -- that -- that disrupts the laminar airflow
15:06:38 25 conditions.

15:06:38 1 Q. Has 3M done any analysis with respect to
15:06:42 2 comparing the disruption of the sterile field by the
15:06:45 3 forced-air warming device as compared to someone
15:06:48 4 moving in the operating room?

15:06:49 5 A. We have not conducted any studies like that.

15:06:52 6 Q. Okay. Do you know what the airflow is of a
15:06:56 7 person walking -- the airflow created by a person
15:06:59 8 walking in the operating room?

15:07:00 9 A. I don't know what the velocity is.

15:07:04 10 Q. Okay. Do you think it's more or less than
15:07:06 11 the air output of a Bair Hugger blanket?

15:07:13 12 MR. BLACKWELL: Object to the form of the
15:07:14 13 question.

15:07:16 14 A. I suspect that it's less, but I don't know.

15:07:20 15 Q. Well do you think a person moving from point
15:07:25 16 A to point B in the operating room is creating an
15:07:28 17 airflow of 30 cfm?

15:07:30 18 MR. BLACKWELL: I object to the -- the form
15:07:32 19 of the question as beyond the scope of the 30(b)(6)
15:07:34 20 designation, and as calling for speculation.

15:07:38 21 A. I mean the total amount of air disrupted or
15:07:41 22 displaced by the movement of a body through -- through
15:07:45 23 a room is probably pretty large. I just don't know
15:07:49 24 what it is.

15:07:50 25 Q. You've never compared it to what the

15:07:53 1 disruption is with a forced-air warming device.

15:07:55 2 MR. BLACKWELL: Objection as asked and
15:07:56 3 answered.

15:07:56 4 A. No.

15:08:01 5 MR. ASSAAD: Take a break. Let's take a
15:08:04 6 break.

15:08:05 7 THE REPORTER: Off the record, please.

15:25:11 8 (Recess taken.)

15:25:11 9 BY MR. ASSAAD:

15:25:15 10 Q. We previously marked as --

15:25:16 11 Exhibit No. 77 is a graph that I think we
15:25:21 12 discussed earlier; is that correct?

15:25:22 13 A. Yes, we did discuss this one. Yeah.

15:25:26 14 Q. And this is the analysis that you did
15:25:28 15 regarding joint infection rates and Bair Hugger unit
15:25:31 16 sales by year; correct?

15:25:32 17 A. Yes.

15:25:33 18 Q. And it goes from 1998 to 2012; correct?

15:25:39 19 A. Yeah, I think the infection rate did.

15:25:43 20 Actually, it's from 1997. But the -- but the Bair
15:25:47 21 Hugger utilization rate is from 1998.

15:25:51 22 Q. And based on the orange line, which is the
15:25:59 23 infection rate; correct?

15:26:00 24 A. Yes.

15:26:01 25 Q. Okay. And with respect to infection rates,

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15:26:09 1 you get the data from the ICD-9 codes -- or did you

15:26:14 2 use the ICD-9 codes to get the data?

15:26:16 3 A. I did.

15:26:17 4 Q. Okay. And I take it on the right-hand side

15:26:24 5 are percentages of infection rates?

15:26:27 6 A. Yeah. It's the deep joint infection rates

15:26:33 7 divided by the procedure codes, so it's a ratio of

15:26:38 8 number of procedures performed in the denominator

15:26:41 9 divided -- or the -- and the infection rate in the

15:26:44 10 numerator.

15:26:45 11 Q. Okay. And the procedure codes are 8151,

15:26:50 12 8152 and 8154?

15:26:53 13 A. Yes.

15:26:54 14 Q. What's 8151?

15:26:55 15 A. I don't remember what they are, but they're

15:27:00 16 primary joint replacements I believe.

15:27:05 17 Q. Did you look at revision joint replacements?

15:27:09 18 A. I did with and without.

15:27:11 19 Q. Okay. Which ones with and which ones

15:27:13 20 without?

15:27:14 21 A. The without, you don't have the --

15:27:15 22 That chart's not here. At least I don't see

15:27:18 23 it.

15:27:18 24 Q. Does that chart exist?

15:27:20 25 A. I believe it does exist.

15:27:21 1 Q. Okay. Is this one primary or -- or
15:27:23 2 revision; do you know?

15:27:24 3 A. This is primary.

15:27:25 4 Q. And how do you know it's primary?

15:27:27 5 A. Because I think the rates are slightly
15:27:29 6 lower --

15:27:32 7 I don't know. I'd have to -- I'd have to
15:27:34 8 again look at the procedure codes to be absolutely
15:27:36 9 certain of that.

15:27:38 10 Q. Okay. Now are you saying here that the
15:27:40 11 primary -- if this is the primary, let's assume that
15:27:43 12 it is because that's your best guess at this time --
15:27:46 13 the primary revision infection rates are between four
15:27:50 14 and five percent?

15:27:50 15 A. Well from -- from approximately 2004 to
15:28:03 16 2012, yes.

15:28:04 17 Q. All right. At some point it was over five
15:28:07 18 percent; correct?

15:28:08 19 A. In 2003 I believe, yes.

15:28:10 20 Q. Okay. And I guess, you know, since 1998 it
15:28:22 21 looks like it's roughly four percent or above;
15:28:25 22 correct?

15:28:25 23 A. Yes.

15:28:28 24 Q. Okay. And I take it the blue line or the --
15:28:34 25 I think that's a blue line -- is the Bair Hugger unit

15:28:36 1 sales?

15:28:37 2 A. Yes.

15:28:39 3 Q. Is that sales or -- or placement, or both?

15:28:43 4 A. It's -- it's unit sales of blankets.

15:28:46 5 Q. Unit sales of blankets. Okay.

15:28:48 6 A. We don't sell the warming units, so I used

15:28:51 7 blankets as a proxy for --

15:28:53 8 Q. Okay.

15:28:53 9 A. -- utilization.

15:28:55 10 Q. Now is it all blankets or a certain type of

15:29:00 11 blanket?

15:29:01 12 A. It was all blankets.

15:29:02 13 Q. Okay. Now you would agree with me that the

15:29:13 14 blanket that is usually used in total hip and total

15:29:16 15 knee is an upper body blanket; correct?

15:29:18 16 A. I -- I believe that's normally correct,

15:29:25 17 although there are other types of blankets that are

15:29:27 18 used in orthopedic surgery.

15:29:30 19 Q. But we're talking here joint infection of

15:29:32 20 total knee and total hip arthroplasty; correct?

15:29:35 21 A. Yes.

15:29:37 22 Q. All right. They don't use pediatric

15:29:39 23 blankets or cardiac blankets for those cases.

15:29:41 24 A. No, they don't.

15:29:44 25 [REDACTED] [REDACTED] [REDACTED]

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15:29:44 1 [REDACTED]

15:29:47 2 [REDACTED]

15:29:53 3 [REDACTED]

15:29:55 4 [REDACTED] [REDACTED]

15:29:56 5 [REDACTED]

15:29:57 6 [REDACTED] [REDACTED]

15:29:59 7 [REDACTED]

15:30:01 8 [REDACTED] [REDACTED]

15:30:04 9 [REDACTED]

15:30:04 10 [REDACTED] [REDACTED]

15:30:05 11 [REDACTED] [REDACTED]

15:30:06 12 [REDACTED] [REDACTED]

15:30:07 13 Q. Okay. What other blanket would be used in a

15:30:10 14 total hip or total knee arthroplasty surgery?

15:30:14 15 A. A lower body.

15:30:16 16 Q. Okay. Do you think a lower body blanket

15:30:19 17 could be used for a total knee?

15:30:20 18 A. Not for a total knee, but for total hip --

15:30:23 19 Q. Okay.

15:30:23 20 A. -- in the anterior approach.

15:30:25 21 Q. Okay. But that's not as common as just

15:30:30 22 using the 522.

15:30:31 23 A. It's less common.

15:30:32 24 Q. Okay. So when you did the Bair Hugger --

15:30:34 25 And this should not be units, it should be

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15:30:36 1 blankets, correct, because when I think of a Bair

15:30:39 2 Hugger unit I think of the blower unit.

15:30:42 3 A. Yeah. Unit here means blankets.

15:30:44 4 Q. [REDACTED]

15:30:48 5 [REDACTED]

15:30:57 6 [REDACTED]

15:31:01 7 [REDACTED]

15:31:04 8 [REDACTED]

15:31:06 9 [REDACTED]

15:31:07 10 [REDACTED]

15:31:09 11 [REDACTED]

15:31:10 12 [REDACTED]

15:31:12 13 [REDACTED]

15:31:14 14 [REDACTED]

15:31:16 15 [REDACTED]

15:31:17 16 [REDACTED]

15:31:19 17 [REDACTED]

15:31:21 18 [REDACTED]

15:31:24 19 [REDACTED]

15:31:27 20 [REDACTED]






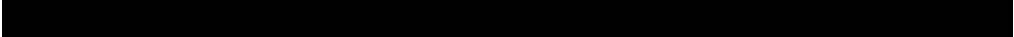



































15:31:32 21 [REDACTED]

15:31:32 22 [REDACTED]

15:31:32 23 [REDACTED]

15:31:34 24 [REDACTED]

15:31:35 25 [REDACTED]

			226
15:31:36	1		
15:31:37	2		
15:31:38	3		
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15:31:49	8		
15:31:50	9		
15:31:59	10		
15:32:02	11		
15:32:04	12		
15:32:09	13		
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15:32:35	1	[REDACTED]
15:32:36	2	[REDACTED] [REDACTED]
15:32:37	3	[REDACTED] [REDACTED] [REDACTED]
15:32:44	4	[REDACTED]
15:32:46	5	[REDACTED] [REDACTED]
15:32:50	6	[REDACTED]
15:32:56	7	[REDACTED] [REDACTED]
15:32:59	8	[REDACTED]
15:33:00	9	[REDACTED]
15:33:02	10	[REDACTED] [REDACTED]
15:33:08	11	[REDACTED] [REDACTED]
15:33:10	12	[REDACTED]
15:33:10	13	[REDACTED] [REDACTED]
15:33:10	14	[REDACTED] [REDACTED]
15:33:12	15	[REDACTED]
15:33:17	16	[REDACTED]
15:33:25	17	[REDACTED] [REDACTED]
15:33:27	18	[REDACTED]
15:33:27	19	[REDACTED] [REDACTED]
15:33:29	20	[REDACTED] [REDACTED]
15:33:31	21	[REDACTED] [REDACTED]
15:33:32	22	[REDACTED] [REDACTED]
15:33:33	23	[REDACTED]
15:33:34	24	[REDACTED] [REDACTED]
15:33:38	25	[REDACTED] [REDACTED]

15:33:41 1 [REDACTED]

15:33:51 2 (Discussion off the stenographic record.)

15:34:05 3 Q. You earlier testified that you -- you used

15:34:10 4 Parvisi's biostatistician to get the data that he used

15:34:14 5 in the 2012 article; correct?

15:34:17 6 A. He -- he sent the data to me, yes.

15:34:20 7 Q. Okay. His data only went up to 2009, so

15:34:35 8 where did you obtain the data from 2009 to 2012?

15:34:38 9 A. I -- I -- I may not have analyzed the

15:34:45 10 infection rate data during those -- during that

15:34:47 11 timeframe.

15:34:50 12 Q. Well you have data points from 2009 to 2012.

15:34:51 13 A. Well this didn't come from Dr. Parvizi.

15:34:55 14 Q. Oh. Then I'm really confused. I thought

15:34:58 15 you said you used his data to create this graph.

15:35:00 16 A. No. I used the NNIS data to the create this

15:35:03 17 graph. I did subsequently a diff -- completely

15:35:07 18 different one --

15:35:08 19 Q. Okay.

15:35:08 20 A. -- using Dr. Parvisi's biostatistician's

15:35:13 21 data.

15:35:14 22 Q. So these infection rates is data that you

15:35:15 23 put together.

15:35:15 24 A. This is data that came from the CDC NNIS

15:35:20 25 database.

15:35:20 1 Q. NIS database.

15:35:21 2 A. Well it's called NNIS. It's now called --

15:35:21 3 it's changed names again, but it used to be the

15:35:26 4 National Nosocomial Infection Survey --

15:35:27 5 Q. Okay.

15:35:28 6 A. -- and that's where I got this data. It has

15:35:30 7 a different name now, they changed the name, but they

15:35:33 8 stopped collecting the data in 2012.

15:35:36 9 Q. Okay. And so your data set was different

15:35:45 10 than the data set that was used by Dr. Freeman;

15:35:49 11 correct?

15:35:49 12 MR. BLACKWELL: Yeah. I object as beyond

15:35:51 13 the scope of the 30(b)(6) designation.

15:35:54 14 A. It -- it seems to be.

15:35:55 15 Q. Why don't you use --

15:35:57 16 When creating this data set, why didn't --

15:35:59 17 why did you not use HCUP or NIH data?

15:36:04 18 MR. GOSS: Same objection.

15:36:05 19 A. I used the data that was publicly available

15:36:07 20 on the -- from the CDC.

15:36:20 21 Q. And 3M was aware that you were performing

15:36:23 22 this analysis; correct?

15:36:24 23 A. No.

15:36:27 24 Q. Did you perform this analysis on 3M's time?

15:36:29 25 MR. BLACKWELL: I object as beyond the scope

15:36:31 1 of his 30(b)(6) designations.

15:36:34 2 A. Yes.

15:36:34 3 Q. Did you report this analysis to anyone at

15:36:36 4 3M?

15:36:37 5 MR. BLACKWELL: Same objection.

15:36:37 6 A. Yes.

15:36:38 7 Q. Gary Hansen; correct?

15:36:40 8 A. No.

15:36:40 9 Q. Who -- who did you report it --

10 Jay Issa?

15:36:43 11 A. Dr. Issa.

15:36:44 12 Q. Okay. Anyone else?

15:36:45 13 MR. BLACKWELL: Same objection.

15:36:46 14 A. I believe it was just Dr. Issa and then the
15:36:50 15 legal team.

15:36:51 16 Q. Okay. Was Jay Issa aware that you were
15:37:02 17 performing this analysis before you gave him the
15:37:03 18 results?

15:37:06 19 MR. BLACKWELL: Same objection, so object as
15:37:07 20 to form.

15:37:07 21 A. Not specifically.

15:37:09 22 Q. What do you mean by "not specifically?"

15:37:12 23 MR. BLACKWELL: Same objection.

15:37:13 24 A. Well he -- I mean he's not aware in -- in --
15:37:18 25 in that level of detail what kind of work I do.

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15:37:22 1 Q. I understand that. But was he aware that
15:37:25 2 you were going to spend some time doing this analysis
15:37:30 3 of infection rates and Bair Hugger sales -- blanket
15:37:33 4 sales?

15:37:34 5 MR. BLACKWELL: Object as beyond the scope
15:37:35 6 of his 30(b)(6) deposition designation, and object as
15:37:40 7 to form.

15:37:41 8 A. No, he was not aware.

15:37:47 9 Q. Okay. Has this chart ever been used in
15:38:03 10 formulating any internal testing regarding surgical-
15:38:10 11 site infections?

15:38:10 12 MR. BLACKWELL: I object as beyond the scope
15:38:11 13 of his 30(b)(6) designation.

15:38:14 14 A. No, it has not been.

15:38:27 15 Q. Now with respect to the Sessler study, I
15:38:31 16 hand you what's been marked as Exhibit No. 226. Do
15:38:46 17 you recognize this spreadsheet on Exhibit 226?

15:38:50 18 A. I don't recall if I've seen this before or
15:38:54 19 not.

15:38:55 20 Q. I represent to you that this is the data
15:38:58 21 that 3M prepared and sent over to Dr. Sessler with
15:39:04 22 respect to the -- the results of the study in
15:39:08 23 Amsterdam, at Amersfoort and Utrecht. Does that
15:39:14 24 refresh your recollection?

15:39:15 25 A. I mean it may be. I -- I -- I'm not sure if

15:39:30 1 I've ever seen this.

15:39:31 2 Q. Okay. You -- you went to Amsterdam;

15:39:35 3 correct?

15:39:35 4 A. Yes.

15:39:36 5 Q. And you actually helped perform the --

15:39:38 6 the inter -- the external --

15:39:40 7 You helped obtain the data from Amsterdam;

15:39:46 8 correct?

15:39:46 9 A. No. I was not involved in that.

15:39:47 10 Q. You were not involved in -- in obtaining the

15:39:50 11 data from LUWA?

15:39:52 12 MR. BLACKWELL: I object as asked and

15:39:53 13 answered.

15:39:53 14 A. No.

15:39:54 15 Q. Were you involved in an analysis of the

15:39:57 16 data?

15:39:57 17 A. No.

15:39:57 18 Q. You mentioned before that only one particle

15:40:01 19 count was greater when the Bair Hugger was on as

15:40:04 20 compared to when the Bair Hugger was off. Looking at

15:40:07 21 the data, do you agree that that was an accurate

15:40:10 22 statement given by 3M previously in this deposition?

15:40:14 23 MR. BLACKWELL: I object to the form of the

15:40:15 24 question, foundation.

15:40:20 25 A. Well I'm not really sure what I'm looking at

15:40:22 1 here.

15:40:34 2 Q. Sitting here today, are you testifying that
15:40:35 3 you are not familiar to discuss the -- your knowledge
15:40:43 4 and analysis of the data that was used and obtained by
15:40:47 5 3M to publish the Sessler study?

15:40:52 6 MR. BLACKWELL: I object to the form of the
15:40:53 7 question, and beyond the scope of his 30(b)(6)
15:40:56 8 designations.

15:41:01 9 A. I -- I'm telling you that I'm not really
15:41:05 10 sure what I'm looking at here.

15:41:07 11 Q. I represent to you that each of the numbers
15:41:09 12 represent particle count, and for -- for Amersfoort
15:41:14 13 and Utrecht they used the 522 and 635 blanket. You
15:41:17 14 were aware of that; correct?

15:41:18 15 A. Yes, I see those designations.

15:41:20 16 Q. And you're aware they had a particle counter
15:41:24 17 that calculated the particle count over the sterile
15:41:26 18 field; correct?

15:41:27 19 MR. BLACKWELL: I object to the line of
15:41:29 20 questioning. The witness is referring to what is
15:41:32 21 marked as Exhibit 226 and he doesn't have personal
15:41:36 22 knowledge of the document, so --

15:41:39 23 MR. ASSAAD: It's the Sessler study, Jerry.

15:41:41 24 MR. BLACKWELL: I understand, Mr. Assaad.
15:41:43 25 The Exhibit 226 you -- you gave him, he's not familiar

15:41:46 1 with it. If you want him to assume that these numbers
15:41:48 2 are accurate and truthful for purposes of your
15:41:51 3 question, you can do that, and perhaps he can answer,
15:41:54 4 but I think he's stuck in just not being familiar with
15:41:57 5 the document.

15:41:57 6 Q. Are you familiar with the Sessler study?

15:41:59 7 A. I'm familiar with the study.

15:42:00 8 Q. Are you able to sit here and testify as to
15:42:02 9 3M's knowledge and analysis of the Sessler study?

15:42:04 10 A. Well we -- we didn't do the analysis of
15:42:07 11 the -- of that study. That was -- that was done by
15:42:10 12 Olmstead and -- and Sessler and the other authors of
15:42:14 13 that paper.

15:42:15 14 Q. You don't think Gary Hansen did the analysis
15:42:17 15 of the -- of the data?

15:42:18 16 A. Well he -- he may have.

15:42:20 17 Q. Okay. So sitting here today, you don't know
15:42:22 18 who did the analysis; correct?

15:42:24 19 A. I don't know personally who conducted the
15:42:25 20 analysis.

15:42:26 21 Q. Well does 3M know who did the analysis?

15:42:28 22 A. I think it's --

15:42:30 23 I think the paper explains who did the
15:42:33 24 analysis. Each of the authors, as -- as part of the
15:42:38 25 disclosure, indicates what they were responsible for

15:42:42 1 in the paper.

15:42:47 2 Q. Are you ready to sit here and discuss the
15:42:50 3 analysis of the data that 3M obtained from LUWA that
15:42:58 4 they used in publishing the Sessler article?

15:43:01 5 MR. BLACKWELL: Object to the form of the
15:43:02 6 question, foundation.

15:43:04 7 A. Well I mean I can -- I can look at this
15:43:07 8 spreadsheet and -- and answer questions.

15:43:08 9 Q. I will represent to you, for -- to speed up
15:43:12 10 things, that this is the raw data that was used by the
15:43:17 11 authors as well as Gary Hansen that was obtained by
15:43:22 12 the studies done in Amsterdam. Assuming that's
15:43:26 13 correct, do you understand what this data is?

15:43:31 14 MR. BLACKWELL: And I object to form.

15:43:34 15 A. Well I -- I mean I can look at the labels on
15:43:37 16 the spreadsheet and see that the -- you have a mean
15:43:40 17 and a standard deviation, and those are probably
15:43:42 18 particle counts, there's a raw PE, which I assume to
15:43:49 19 mean protective effect, and a final protective effect.
15:43:52 20 I don't know why there's a -- I don't know why there's
15:43:54 21 a difference, but I'll assume that there's some
15:43:57 22 calculation that makes that possible. Looks like
15:44:03 23 they're almost always nearly the same.

15:44:09 24 Q. Okay. You understand what a protective
15:44:12 25 effect is; correct?

15:44:12 1 A. Yes.

15:44:13 2 Q. Okay. And the lower --

15:44:15 3 The higher the protective effect, the better
15:44:23 4 the laminar flow system; correct?

15:44:29 5 MR. BLACKWELL: I object to the form of the
15:44:30 6 question.

15:44:31 7 MR. ASSAAD: Basis?

15:44:32 8 A. The better it is at removing particulates
15:44:34 9 from the -- wherever these were sampled at the --

15:44:37 10 Q. Yes.

15:44:38 11 A. -- surgical site.

15:44:39 12 Q. So the higher the number, the better it
15:44:42 13 removes particulates; correct?

15:44:43 14 A. The better the protective effect, yes.

15:44:45 15 Q. Yes. So a higher the protective effect is
15:44:49 16 better with respect to an operating room theater.

15:44:49 17 A. In theory.

15:44:50 18 Q. And in reality.

15:44:52 19 A. I -- I'm not sure I would agree with that.

15:44:57 20 Q. So you don't agree that an increased amount
15:45:03 21 of particle removed by an op -- particle removal by an
15:45:06 22 operating room is -- has no relation to the quality of
15:45:15 23 the operating room?

15:45:16 24 MR. BLACKWELL: I object to the form of the
15:45:18 25 question, and I object as beyond the scope of the

15:45:20 1 30(b)(6) notice.

15:45:24 2 MR. ASSAAD: So it goes to the analysis of
15:45:25 3 the sterile field, third-party testing.

15:45:27 4 MR. BLACKWELL: I don't think so, so I state
15:45:29 5 my objection for the record.

15:45:31 6 A. So the -- the relationship of the protective
15:45:34 7 effect to the quality of the operating room air is
15:45:39 8 somewhat controversial given the large retrospective
15:45:43 9 analyses that are done by Brandt and -- and Hooper
15:45:48 10 that -- that at least provide compelling evidence
15:45:52 11 that -- that even when extreme measures are taken to
15:45:58 12 reduce particulates in the operating room, it doesn't
15:46:00 13 have any effect on reducing the risk of a subsequent
15:46:04 14 surgical-site infection. So that's my --

15:46:07 15 My answer to your question is based on that
15:46:10 16 knowledge.

15:46:10 17 Q. Well are you familiar with the article
15:46:12 18 written by Darouiche?

15:46:16 19 A. I -- not --

15:46:17 20 The author is not familiar to me.

15:46:20 21 Q. Darouiche, Green, University of Texas?

15:46:23 22 A. I'm not familiar with that.

15:46:25 23 Q. Comparing CFU counts to surgical-site in --
15:46:28 24 to deep joint infections?

15:46:30 25 MR. BLACKWELL: Objection to the question as

15:46:31 1 beyond the scope of the 30(b)(6) designation.

15:46:32 2 MR. ASSAAD: You opened the door.

15:46:35 3 A. I'm not familiar with that paper that I --

4 Q. Okay.

15:46:36 5 A. -- that I know.

15:46:37 6 Q. All right. You mentioned before in your
15:46:39 7 testimony that there was only one instance in -- where
15:46:41 8 the particle count in the -- in the Amsterdam studies
15:46:45 9 was greater for the Bair Hugger being on as compared
15:46:47 10 to being off. Looking at this data, do you believe
15:46:50 11 that accurate -- that the statement you said
15:46:52 12 previously was correct?

15:46:58 13 MR. BLACKWELL: I object to any assessment
15:47:00 14 or analysis of Exhibit 226 as beyond the scope of the
15:47:04 15 30(b)(6) designation for this witness.

15:47:26 16 A. So as I look at the data in this spreadsheet
15:47:28 17 in Exhibit 226, the protective effects listed here
15:47:36 18 when the warming unit is off are all higher than they
15:47:41 19 are when either the ambient or the warm temperature
15:47:45 20 setting is selected.

15:47:46 21 Q. And would it be fair to state, in ana --
15:47:50 22 analyzing this data, is that when the Bair Hugger is
15:47:53 23 on, whether on ambient or warm, it decreases the
15:47:56 24 protective effect of the operating room used in
15:48:01 25 Amersfoort and Utrecht?

15:48:03 1 MR. BLACKWELL: Same objection.

15:48:05 2 A. Well except in the case of the 635 in
15:48:06 3 Utrecht, it's identical.

15:48:08 4 Q. Okay. So except for the 635 in Utrecht, the
15:48:12 5 522 and 635 in Amersfoort and the 522 in Utrecht, when
15:48:17 6 the Bair Hugger unit's on, whether it's ambient or
15:48:19 7 warm, reduces the protective effect as compared to
15:48:22 8 when it's off.

15:48:23 9 MR. BLACKWELL: Same objection.

15:48:25 10 A. The -- the numbers here would indicate that.

15:48:54 11 Q. Okay. Another article you mentioned was
15:48:56 12 Avidan, which is with respect to surgical site --
15:49:10 13 disruption of the surgical site. Do you recall
15:49:13 14 mentioning that article --

15:49:13 15 A. Yes.

15:49:13 16 Q. -- that 3M acknowledge and analyzed?

15:49:17 17 A. We're aware of that paper, yes.

15:49:19 18 Q. Okay. Are there any flaws in the Avidan
15:49:21 19 study?

15:49:22 20 A. Again, every -- every study has flaws.

15:49:28 21 Q. Yes, but I'm asking about the Avidan study
15:49:30 22 right now.

15:49:31 23 A. I'm certain that we could find flaws in that
15:49:34 24 paper.

15:49:36 25 Q. Avidan found that the internal components of

15:49:39 1 the Bair Hugger unit were contaminated; correct?

15:49:40 2 A. I think he confirmed that the filter had
15:49:45 3 contamination on the exterior surface.

15:49:55 4 Q. Do you not agree that the proximate hose
15:50:03 5 swabs grew bacteria on it, as well as the distal
15:50:09 6 hose -- hose swabs?

15:50:09 7 A. Yes.

15:50:10 8 Q. Okay. As well as the outer surfaces of the
15:50:12 9 filter; correct?

15:50:12 10 A. Yes.

15:50:13 11 Q. And you agree with me that Avidan also
15:50:15 12 showed particles and bacteria coming out of the hose;
15:50:17 13 correct?

15:50:17 14 A. Particles, I --
15:50:21 15 I don't believe he showed particles, he
15:50:23 16 did --

15:50:23 17 Q. Correct.

15:50:24 18 A. -- increased CFU counts.

15:50:26 19 Q. My fault. You're correct. Increased CFU
15:50:31 20 counts coming out of the hose; correct?

15:50:32 21 A. Yes.

15:50:32 22 Q. And one of the weaknesses or flaws of Avidan
15:50:34 23 is that they only had eight units tested; correct?

15:50:40 24 A. That could be a -- that could be a flaw: a
15:50:44 25 small number.

15:50:45 1 Q. Okay. Do you know whether or not it was a
15:50:48 2 505 or the 750 used in Avidan?

15:50:51 3 A. I believe it was a 505, but I'm not certain.

15:50:58 4 Q. And another flaw with respect to Avidan is
15:51:09 5 when they did put the blankets on, they only did that
15:51:12 6 test with only two blankets to see whether or not
15:51:15 7 bacteria would come out of the holes in the blanket;
15:51:17 8 correct?

15:51:17 9 A. Yes.

15:51:18 10 Q. In your analysis of Avidan, is there any
15:51:30 11 scientific reasoning as to why the authors could not
15:51:43 12 detect bacteria that was coming out of the Bair Hugger
15:51:48 13 hose, could not detect it out of the blanket?

15:51:54 14 MR. BLACKWELL: Object to the form of the
15:51:56 15 question.

15:51:56 16 Q. Do you understand my question?

15:51:57 17 A. I understand your question.

15:51:59 18 Q. Okay.

15:51:59 19 A. Well in the first place, the way in which
15:52:02 20 Avidan looked at particulates being emitted from the
15:52:07 21 end of the hose was likely to entrain air around the
15:52:12 22 hose when -- when he held the hose over the -- over
15:52:15 23 the plate, so it's not completely convincing that the
15:52:19 24 particulates that were recovered in the settle plates
15:52:22 25 came from the hose. They may have come from another

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15:52:26 1 source and been entrained in that air that was being
15:52:29 2 blown on the plates. So I mean it's entirely possible
15:52:32 3 that the -- had the experiment been done differently,
15:52:35 4 that they would have discovered that the air coming
15:52:38 5 out of the hose end was also sterile. So that's one
15:52:43 6 scientific hypothesis.

15:52:48 7 Q. So that -- that's -- that's a -- you
15:52:50 8 consider a seriously -- serious flaw of Avidan.

15:52:53 9 A. It --

15:52:54 10 Yeah, it could be.

15:52:54 11 Q. Okay. What's 3M's position on it? Is it or
15:52:58 12 is it not a serious flaw?

15:52:59 13 A. It's a flaw.

15:53:00 14 Q. Okay. Would you consider it a serious flaw?

15:53:02 15 A. Well I think it's more important that they
15:53:04 16 were unable to recover any bacteria when the ho --
15:53:07 17 when the blanket was put on the end of the hose other
15:53:10 18 than -- rather than the fact that they were able to
15:53:12 19 show that a hose in free air was able to entrain
15:53:18 20 bac -- bacteria.

15:53:20 21 Q. Now can you answer my question. Do you
15:53:23 22 believe that was a serious flaw, the fact that the --
15:53:25 23 the way they collected data out of the hose also
15:53:28 24 pulled air -- possibly pulled air from outside of the
15:53:31 25 hose?

15:53:32 1 A. Yeah.

15:53:32 2 MR. BLACKWELL: Object as asked and
15:53:33 3 answered.

15:53:33 4 Q. With respect to -- you -- you would -- you
15:53:41 5 would expect -- strike that.

15:53:42 6 The method used to detect bacteria coming
15:53:46 7 out of the blanket is also flawed; correct?

15:53:52 8 A. Potentially.

15:53:54 9 Q. Well it's a settle plate that was -- it
15:53:57 10 was --

15:53:57 11 You have a thousand holes coming out of the
15:54:00 12 Bair Hugger 522 blanket; correct?

15:54:01 13 A. I don't know what the number is.

15:54:03 14 Q. A large number.

15:54:04 15 A. Yes.

15:54:05 16 Q. Okay. You'd agree with me that unless you
15:54:09 17 could control all of the -- test all the air that's
15:54:13 18 coming out of the wide blanket, that you're just
15:54:16 19 basically doing random chance of trying to detect
15:54:19 20 bacteria coming out of the blanket.

15:54:21 21 A. Yes.

15:54:22 22 Q. And that's another serious flaw.

15:54:24 23 A. Well sampling is a frequently-used
15:54:28 24 scientific method to estimate. When -- when you can't
15:54:32 25 measure an entire quantity of something, estimation is

15:54:37 1 a -- a completely acceptable method.

15:54:41 2 Q. I understand that. But when you're going to
15:54:43 3 estimate and do sampling, I mean having only two tests
15:54:47 4 is a very low number and also indicates a serious
15:54:51 5 flaw.

15:54:51 6 MR. BLACKWELL: Object to the form of the
15:54:53 7 question.

15:54:53 8 A. I don't know if it's a serious flaw, but
15:54:56 9 it's --

15:54:57 10 A low number could -- could confound the
15:54:59 11 data.

15:55:14 12 Q. And Avidan suggested that a microbial filter
15:55:33 13 could be fitted to the nozzle of the hose to prevent
15:55:36 14 the risk of contamination; correct?

15:55:39 15 MR. BLACKWELL: Object to the form of the
15:55:40 16 question.

15:55:40 17 A. I -- I think he said it could be, yes.

15:55:42 18 Q. And has 3M analyzed that recommendation?

15:55:44 19 A. No.

15:55:48 20 Q. Okay.

15:56:07 21 A. I'll amend my last answer. You asked me if
15:56:11 22 we'd considered or we evaluated --

15:56:13 23 Q. Evaluated, analyzed, considered.

15:56:15 24 A. So we -- we certainly -- we certainly looked
15:56:18 25 at patent applications from Scott Augustine that

15:56:24 1 described a method just like Avidan suggested, so
15:56:28 2 we had -- we were aware of at least a patent
15:56:31 3 application from Scott Augustine.

15:56:34 4 Q. [REDACTED]

15:56:35 5 [REDACTED]

15:56:36 6 [REDACTED]

15:56:39 7 [REDACTED]

15:56:42 8 [REDACTED].

15:56:43 9 Q. Okay. You also mentioned the Kimberger
15:56:58 10 article; correct?

15:56:58 11 A. Yes.

15:56:59 12 Q. That article did not deal with total hip or
15:57:02 13 total knee arthroplasties; correct?

15:57:04 14 A. That's correct.

15:57:05 15 Q. Okay. Deals for shorter orthopedic
15:57:07 16 surgeries; correct?

15:57:07 17 A. Yes.

15:57:08 18 Q. And the sample size was also very small;
15:57:10 19 correct?

15:57:10 20 A. Around 80 subjects I believe.

15:57:12 21 Q. Which, you know, based on your discussions
15:57:14 22 with other scientists in the field, to do an analysis
15:57:24 23 on surgical-site infections, deep joint infections,
15:57:27 24 you need a large number of patients.

15:57:29 25 A. Well that's not what the outcome of the

15:57:31 1 Kimberger article was, though, or the Kimberger study.

15:58:04 2 Q. And you talked about the Kimberger study,
15:58:06 3 and that was published in January of -- or accepted in
15:58:12 4 February of 2017; correct?

15:58:14 5 A. Yes.

15:58:15 6 Q. And actually, Kimberger said his study was
15:58:28 7 inconclusive and more studies are needed and
15:58:32 8 warranted.

15:58:32 9 A. Yes.

15:58:33 10 MR. BLACKWELL: I object to the form of the
15:58:34 11 question.

15:58:40 12 Q. And to have an SSI end point would have
15:58:43 13 required a much larger setup since SSIs are rare in
15:58:47 14 the study's particulate patient population; correct?

15:58:50 15 MR. BLACKWELL: Same objection.

15:58:52 16 A. If surgical-site infections were the primary
15:58:55 17 outcome, a large number of -- of subjects would have
15:58:58 18 been needed. That wasn't the primary outcome in the
15:59:01 19 Kimberger study.

15:59:02 20 Q. What -- what -- what's your understanding of
15:59:04 21 the primary outcome?

15:59:05 22 A. The CFU counts.

15:59:28 23 Q. Do you know what type of -- strike that.

15:59:35 24 Do you know what type of surgeries were
15:59:48 25 used -- or performed in this study?

15:59:50 1 A. They were minor orthopedic procedures.

15:59:53 2 Q. Okay. Were there any implant procedures?

15:59:58 3 A. I -- I don't recall what the procedures were

16:00:00 4 now.

16:00:23 5 Q. Is Kimberger on the advisory panel for 3M?

16:00:31 6 A. I don't believe that he's on an advisory

16:00:33 7 panel for 3M.

16:00:34 8 Q. Does he have any relationship with 3M?

16:00:37 9 A. He is a member of the Outcomes Research

16:00:39 10 Consortium, but that -- that is as close as he gets to

16:00:44 11 3M.

16:00:49 12 Q. Real quick. Going back to Avidan, you agree

16:00:53 13 with me that there's a lack of statistical evidence

16:00:58 14 with respect to the Avidan results; correct?

16:01:00 15 MR. BLACKWELL: Object to form of the

16:01:02 16 question.

16:01:03 17 A. I'm not sure what you mean.

16:01:12 18 Q. There was only two blankets that were tested

16:01:15 19 with respect to whether or not they could find any

16:01:17 20 bacteria on agar plates; correct?

16:01:20 21 A. Yes.

16:01:21 22 Q. Okay. Was there a p-value that was

16:01:25 23 calculated to determine whether or not that was

16:01:27 24 statistically significant?

16:01:28 25 A. Yes.

16:01:29 1 Q. And what was the outcome?

16:01:30 2 A. There was --

16:01:35 3 Now we're talking about Avidan.

16:01:36 4 Q. Yes.

16:01:36 5 A. There was no difference in the --

16:01:40 6 There was no statistical difference.

16:01:42 7 Q. The p-value was above .05.

16:01:45 8 A. Yes.

16:01:45 9 Q. Okay. So basically the hypothesis was not

16:01:54 10 proven or disproven when you have a p-value above .05.

16:02:05 11 A. It was --

16:02:05 12 MR. BLACKWELL: Object to the form of the

16:02:05 13 question.

16:02:06 14 A. The evidence did not support a difference.

16:02:14 15 Q. But there was -- but the p-value also --

16:02:16 16 there was not --

16:02:17 17 The study was to determine whether or not

16:02:18 18 there was a difference or not. The null hypothesis,

16:02:21 19 that there was no difference; correct?

16:02:22 20 A. Yes.

16:02:22 21 Q. Okay. And by having a p-value above .05,

16:02:27 22 you're showing no statistically significant

16:02:30 23 difference, if any, with respect to the data sets;

16:02:32 24 correct?

16:02:32 25 A. Cannot reject the null hypothesis.

16:02:34 1 Q. Okay. But the fact that you could -- the
16:02:39 2 fact that you could not reject the null hypothesis
16:02:41 3 does not mean or indicate that the null hypothesis is
16:02:45 4 true; correct?

16:02:49 5 A. That's -- that's correct.

16:02:55 6 Q. So the mere fact that you cannot conclude
16:03:00 7 that bacteria does not come out of the blankets does
16:03:05 8 not mean that you also -- that you therefore can
16:03:07 9 conclude that bacteria does not come out of the
16:03:09 10 blanket.

16:03:10 11 MR. BLACKWELL: Object to the form of the
16:03:11 12 question.

16:03:14 13 A. Well I mean I -- the --

16:03:21 14 I think as far as we can go is that the data
16:03:23 15 does not support the rejection of the null hypothesis.

16:03:26 16 Q. Yes. But doesn't prove the null hypothesis
16:03:29 17 is true.

16:03:29 18 A. No, it doesn't do that.

16:03:30 19 Q. Okay. So you can't say it's true that
16:03:32 20 bacteria does not come out of the blankets based on
16:03:34 21 the Avidan study; correct?

16:03:36 22 A. Statistically, no.

16:03:37 23 Q. Okay. Now you agree with me that the Legg
16:03:54 24 article showed an increase in particle counts over the
16:03:57 25 sterile field; correct?

16:03:58 1 A. Yes.

16:04:00 2 Q. Okay. As well as the McGovern article;
16:04:03 3 correct? The McGovern/Reed article; correct?

16:04:05 4 A. Yes.

16:04:05 5 Q. By the way, why did you read the McGovern
16:04:08 6 and Reed depositions in preparation of today's
16:04:10 7 testimony?

16:04:11 8 A. They were among the few that I haven't read.

16:04:17 9 Q. I thought you said in preparation of today's
16:04:19 10 deposition you read Reed and McGovern.

16:04:21 11 A. Yes.

16:04:21 12 Q. Okay. Why did you --

16:04:24 13 Is -- is there any reason why you read those
16:04:26 14 two articles in preparation of today's testimony?

16:04:30 15 MR. BLACKWELL: I object as asked and
16:04:30 16 answered.

16:04:30 17 A. They were among the few that I have never
16:04:32 18 read.

16:04:32 19 Q. Okay. So it was just depositions that
16:04:36 20 you -- that you haven't read, but you didn't
16:04:38 21 specifically read them in preparation for your
16:04:42 22 deposition testimony today; is that fair?

16:04:47 23 A. Yeah, that's fair.

16:04:48 24 Q. Okay. And you mentioned Memarzadeh as CFD
16:05:14 25 testing, and you agree with me that the Memzar --

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16:05:17 1 Memarzadeh article showed a slight increase in the
16:05:19 2 disruption of the sterile surgical field; correct?

16:05:23 3 MR. BLACKWELL: I object to the form of the
16:05:24 4 question.

16:05:27 5 A. I don't recall that that's what -- that he
16:05:30 6 found.

16:05:39 7 Q. So you agree with me that, with respect to
16:05:43 8 surgical-site disruption, that Sessler, McGovern and
16:05:56 9 Legg studies that looked at this issue show an
16:05:58 10 increase in particle counts over the surgical site.

16:06:03 11 MR. BLACKWELL: Object to form.

16:06:08 12 A. Well in -- in absolute numbers, in absolute
16:06:12 13 particle count, it's true for the Sessler study except
16:06:17 14 for the 635 blanket at -- at Utrecht.

16:06:20 15 Q. Which was equal; correct?

16:06:22 16 A. They're equal.

16:06:23 17 Q. Legg showed the same thing; correct? Both
16:06:25 18 of his articles showed an increase in particle counts.

16:06:28 19 A. I believe that's correct.

16:06:28 20 Q. And McGovern showed an increase in particle
16:06:31 21 counts; correct?

16:06:31 22 A. Yes.

16:06:31 23 Q. And would you agree with me that, based on
16:06:34 24 these studies and even the Sessler study, that
16:06:37 25 forced-air warming has an effect on the sterile field?

16:06:43 1 MR. BLACKWELL: I object to form.

16:06:52 2 A. Well again, the study that was done in
16:06:56 3 Amersfoort and Utrecht is not from particles generated
16:07:01 4 by the forced-air warming unit, those are particles
16:07:03 5 that were generated external to the surf -- to the
16:07:07 6 patient with the operation of the forced-air warming
16:07:09 7 unit, and in the time period that the data was
16:07:16 8 collected there were either essentially no differences
16:07:19 9 or equal amounts of particles in those -- in that
16:07:23 10 study.

16:07:30 11 Q. Well you would agree with me, in every time
16:07:32 12 the Bair Hugger unit is on the warm setting, even on
16:07:35 13 the 635, that there's always more particles over the
16:07:40 14 sterile field than when the Bair Hugger is off.

16:07:42 15 A. No, I wouldn't agree with that. In Utrecht,
16:07:45 16 the 635, the protective effect when the unit was off
16:07:49 17 is 4.7 -- oh, sorry. I --

16:07:52 18 Yes, that is correct. The -- the -- when
16:07:55 19 it's off, the protective effect is higher --

16:07:58 20 Q. Okay.

16:07:58 21 A. -- than it is when it's on.

16:07:59 22 Q. And if you look at the averages, because
16:08:02 23 that's how they protect -- they get the protective
16:08:04 24 effect, the forced-air warming when the Bair Hugger is
16:08:06 25 warm, in every single study it has more particles over

16:08:10 1 the sterile field than when the Bair Hugger is off.

16:08:13 2 MR. BLACKWELL: I object to the form of the
16:08:15 3 question, and beyond the scope of the 30(b)(6)
16:08:17 4 designations.

16:08:25 5 A. Well I mean actually not in every case. I
16:08:28 6 mean if you look at the --

16:08:29 7 Q. If you look at the averages.

16:08:30 8 A. The averages, yes. But if you look at the
16:08:33 9 cases that go into those averages, that's not correct.
16:08:36 10 There are several where the -- the number of particles
16:08:41 11 recovered in the -- under ambient conditions and warm
16:08:43 12 conditions are lower than they are during the off
16:08:47 13 condition.

16:08:52 14 Q. For some. But you --

16:08:54 15 That's why when you do sampling you look at
16:08:57 16 averages; correct?

16:08:57 17 A. Yes, right.

16:08:58 18 Q. Because there's many factors and you try a
16:09:01 19 get an average; correct?

16:09:02 20 A. Yes.

16:09:02 21 Q. And you agree with me that the average here,
16:09:04 22 every single mean -- which means average, correct,
16:09:07 23 "mean" is equal to "average" --

16:09:10 24 A. Yes.

16:09:10 25 Q. -- indicates that the -- when the Bair

16:09:10 1 Hugger is on, the average -- the average particles are
16:09:13 2 higher when the Bair Hugger is off; correct?

16:09:17 3 MR. BLACKWELL: Same objection, beyond the
16:09:18 4 scope of the 30(b)(6) designation.

16:09:21 5 A. I would agree that the averages are that
16:09:24 6 way, yes.

16:09:24 7 Q. And you agree that every single -- every
16:09:27 8 time the Bair Hugger is on, the protective effect is
16:09:30 9 lower than when the Bair Hugger is off.

16:09:32 10 MR. BLACKWELL: Same objections.

16:09:39 11 A. Except when it's exactly the same.

16:09:41 12 Q. When the Bair Hugger is on compared to off.

16:09:44 13 A. Yes.

16:09:45 14 Q. Where do you see it being exactly the same?

16:09:48 15 A. When it's on ambient temperature in Utrecht
16:09:52 16 with the 635.

16:09:53 17 Q. Oh, you are correct. When the Bair Hugger
16:09:54 18 is on warm as compared to it's off.

16:09:57 19 MR. BLACKWELL: Same objection.

16:09:57 20 A. In the warm condition, yes.

16:09:59 21 Q. Okay. And therefore, you would agree with
16:10:03 22 me that, based on the study that 3M paid for, that the
16:10:09 23 Bair Hugger has an effect, when the Bair Hugger is on
16:10:12 24 warm, has an effect on the protective effect.

16:10:15 25 MR. BLACKWELL: I object that -- to the form

16:10:17 1 of the question and move to strike the comment about
16:10:22 2 the study being paid for.

16:10:25 3 A. I'm sorry, would you repeat the question?

16:10:27 4 Q. You agree with me that 3M paid for the
16:10:31 5 study; correct?

16:10:31 6 MR. BLACKWELL: I object and move --

16:10:34 7 Object to the form of the question.

16:10:35 8 MR. ASSAAD: Basis?

16:10:37 9 MR. BLACKWELL: "Paid for." 3M didn't pay
16:10:38 10 for the study, they funded a study.

16:10:40 11 MR. ASSAAD: Okay.

16:10:41 12 Q. 3M funded the study; correct?

16:10:43 13 MR. BLACKWELL: They didn't go out and buy a
16:10:45 14 study.

16:10:45 15 Q. 3M funded the study; correct?

16:10:47 16 A. Yes.

16:10:47 17 Q. And 3M --

16:10:49 18 A. [REDACTED]

16:10:53 19 [REDACTED]

16:10:54 20 [REDACTED]

16:10:56 21 [REDACTED]

16:10:56 22 [REDACTED]

16:10:59 23 [REDACTED]

16:11:03 24 [REDACTED]

16:11:04 25 [REDACTED]

16:11:04 1 [REDACTED]

16:11:07 2 [REDACTED]

16:11:08 3 [REDACTED]

16:11:08 4 [REDACTED]

16:11:11 5 [REDACTED]

16:11:11 6 [REDACTED]

16:11:11 7 Q. Okay. And therefore, you agree with me that

16:11:15 8 the 3M-funded study here in Sessler indicates that

16:11:19 9 when the Bair Hugger is on warm as compared to the

16:11:22 10 Bair Hugger off, it has an effect on the -- on the

16:11:26 11 particle counts of the sterile field.

16:11:29 12 A. I would agree that the -- the particles are

16:11:33 13 higher -- the particle counts are higher when the unit

16:11:36 14 is on --

16:11:36 15 Q. Warm.

16:11:37 16 A. -- under those conditions, yeah.

16:11:38 17 Q. Okay. And you agree with me that both Legg

16:11:41 18 and McGovern also indicate higher particle counts or

16:11:44 19 bubble counts when the Bair Hugger is on warm as

16:11:47 20 compared to the Bair Hugger is off.

16:11:48 21 MR. BLACKWELL: Object to the form of the

16:11:49 22 question.

16:11:51 23 A. Yes.

16:11:52 24 Q. So based on all those studies, you agree

16:11:55 25 with me that the Bair Hugger, when it's blowing warm

16:12:08 1 air, has an effect on the particle counts in the
16:12:13 2 sterile field.

16:12:14 3 MR. BLACKWELL: Same objection.

16:12:18 4 A. It --

16:12:19 5 I mean it's possible that -- that that's one
16:12:21 6 conclusion you could draw from this data.

16:12:23 7 Q. Well every single study indicates that, so
16:12:26 8 what is your basis that it's possible and not
16:12:28 9 probable?

16:12:29 10 MR. BLACKWELL: Object and move to strike
16:12:31 11 counsel's comment/statement. Object to the form of
16:12:34 12 the question.

16:12:34 13 A. Again, the -- the study at Amersfoort is a
16:12:39 14 different type of study than that conducted by Legg.
16:12:43 15 The -- the study at -- in Amersfoort looked at
16:12:47 16 externally-generated particles in the sterile field;
16:12:51 17 Legg looked at, ostensibly, particles being generated
16:12:55 18 by the forced-air warming unit itself, so it's a
16:12:58 19 different --

16:12:59 20 These are different kinds of studies.

16:13:01 21 Q. Legg and McGovern used bubble counts and --
16:13:03 22 and particle counters.

16:13:04 23 A. Oh, sorry. Yeah. Okay.

16:13:05 24 Q. I mean we're --

16:13:06 25 It doesn't matter where the particles are

16:13:08 1 coming from. Okay? Because particles are all over
16:13:10 2 the operating room and underneath the operating room
16:13:12 3 table and everywhere. Do you agree?

16:13:14 4 A. Yes.

16:13:14 5 Q. Okay. Based on the data that we have today,
16:13:17 6 including the study funded by 3M as well as other
16:13:22 7 studies, every single study indicates that the Bair
16:13:26 8 Hugger increases the particle count over the sterile
16:13:28 9 field; correct?

16:13:30 10 A. In absolute numbers, yes.

16:13:32 11 Q. Yes. Okay. And you have no internal
16:13:50 12 studies to refute that; correct?

16:13:57 13 A. No, we don't.

16:14:29 14 Q. What's defendants' knowledge and analysis of
16:14:33 15 third-party testing regarding whether or not the Bair
16:14:36 16 Hugger causes surgical-site infection?

16:14:49 17 A. Well again, the analysis that I showed you
16:14:52 18 that was done with the CDC data, for example. And the
16:15:01 19 secular trend of deep joint infection over the last
16:15:05 20 decade or so has generally declined in hip and knee
16:15:11 21 implant surgery, so at a -- at a macro level there
16:15:17 22 doesn't appear to be an increase in the number of
16:15:20 23 these infections despite the fact that patients are
16:15:24 24 generally older and sicker and there are more of them
16:15:28 25 now than there were a decade ago.

16:15:47 1 Q. I don't see a decrease in Exhibit 77 of
16:15:50 2 infection rates. Do you?

16:15:54 3 A. Well they haven't --

16:15:56 4 So in this particular exhibit the -- the
16:15:58 5 rates haven't changed dramatically from, say, 1998 or
16:16:02 6 1997 to 19 -- or to 2012, but if you look at the -- if
16:16:08 7 you look at the second one that I have done using the
16:16:11 8 data from Parvizi, there clearly is a trend in -- of
16:16:16 9 decreased surgical-site infections, and it's more in
16:16:19 10 line with the kinds of infection rates that we see at
16:16:22 11 individual institutions in the United States.

16:16:25 12 Q. Are we talking about the 2001-to-2009 data?

16:16:28 13 A. The latest paper, whichever -- whichever
16:16:31 14 data set that is.

16:16:33 15 Q. Okay. Well his own paper showed an increase
16:16:38 16 over the -- from 2001 to 2009. Even though it was a
16:16:42 17 slight increase, it was an increase.

16:16:43 18 A. No, I don't think that's correct. The data
16:16:45 19 that I have shows a -- a clear decline in infection --
16:16:48 20 in joint infection rates over that time period.

16:16:53 21 Q. I want to print up that article for you.
16:16:56 22 We'll move on and I'll get it printed up and we can
16:16:59 23 talk about it.

16:17:07 24 We're talking about the 2012 article;
16:17:09 25 correct?

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16:17:09 1 A. I believe that's the corr -- yeah, I believe
16:17:13 2 that's the correct one.

16:17:14 3 Q. Any other articles or studies that you rely
16:17:17 4 upon with respect to third-party testing regarding
16:17:22 5 surgical-site infection?

16:17:29 6 A. Well the Kimberger article would -- for
16:17:32 7 example, although that's not surgical-site infection,
16:17:35 8 but --

16:17:39 9 Q. I guess a preface -- I don't mean to
16:17:41 10 interrupt -- I want to talk about total hip and total
16:17:43 11 knee arthroplasty.

16:17:45 12 A. Yes.

13 Q. Okay.

16:17:45 14 A. Right.

16:17:45 15 Q. Isn't it true that there's a pilot study
16:17:51 16 being performed right now funded by 3M in the U.K.?

16:17:54 17 A. Yes.

16:17:54 18 Q. Okay. Is that study started?

16:17:57 19 A. I don't think it started recruiting yet.

16:18:00 20 Q. Okay. And that's going to look at
16:18:06 21 surgical-site infections for a certain type of
16:18:08 22 orthopedic surgery; correct?

16:18:11 23 A. Yes, as one of the outcomes.

16:18:11 24 Q. And one of the investigators is Mike Reed;
16:18:14 25 correct?

16:18:14 1 A. Yes.

16:18:15 2 Q. Okay. And 3M, in its analysis of studies,
16:18:25 3 has actually criticized Mike Reed; correct?

16:18:27 4 A. Yes.

16:18:36 5 MR. BLACKWELL: I think this is a place for
16:18:39 6 a break.

16:18:39 7 MR. ASSAAD: Sure.

16:18:40 8 THE REPORTER: Off the record, please.

16:35:20 9 (Recess taken.)

16:35:20 10 BY MR. ASSAAD:

16:35:22 11 Q. With respect to surgical-site infections and
16:35:27 12 3M's knowledge and analysis, you would agree with me
16:35:29 13 that there's no reliable study out there that
16:35:31 14 indicates that normothermia reduces the incidence of
16:35:39 15 periprosthetic joint infections; correct?

16:35:42 16 MR. BLACKWELL: Object to the form of the
16:35:44 17 question.

16:35:44 18 A. In that particular surgery, I don't believe
16:35:51 19 there are any randomized controlled trials that looked
16:35:56 20 at that question.

16:35:56 21 Q. There's no studies that looked at that
16:35:58 22 question; correct?

16:35:59 23 MR. BLACKWELL: Same objection.

16:36:00 24 A. There may be some retrospective studies, but
16:36:03 25 I -- I don't recall any right now.

16:36:06 1 Q. Well sitting -- yeah. Sitting here today,
16:36:07 2 does 3M have any knowledge or any analysis of any
16:36:10 3 studies that indicate that maintaining normothermia
16:36:15 4 reduces the incidence of periprosthetic joint
16:36:18 5 infections?

16:36:19 6 A. No.

16:36:19 7 Q. And it's true that 3M is aware, since 2012,
16:36:23 8 that the Kurz study that it relies upon, stating
16:36:27 9 maintaining normothermia reduces the incidence of
16:36:30 10 surgical-site infection, is no longer reliable.

16:36:32 11 MR. BLACKWELL: Object to form of the
16:36:34 12 question.

16:36:35 13 A. No, we're not aware of that. I -- I mean
16:36:38 14 the study is as reliable now as it was then.

16:36:40 15 Q. So you don't recall -- you yourself, an
16:36:44 16 employee of 3M -- attending a KOL meeting in
16:36:48 17 Washington D.C. in 2012 in which the authors of the
16:36:51 18 Kurz study indicated that the study that -- on
16:37:00 19 colorectal patients is no longer -- no longer reliable
16:37:04 20 in 2012 scientific standards?

16:37:06 21 MR. BLACKWELL: I object to the form of the
16:37:07 22 question.

16:37:10 23 A. I -- I do not recall them saying that in my
16:37:13 24 presence. And I'm not even sure I remember being at a
16:37:16 25 meeting in Washington, D.C.

16:37:18 1 Q. Okay. Have you read Andrea Kurz's
16:37:20 2 deposition?

16:37:21 3 A. No.

16:37:21 4 Q. Okay. You agree with me that, with respect
16:37:24 5 to maintaining normothermia, that Andrea Kurz and Dr.
16:37:29 6 Sessler are the leading researchers in that area.

16:37:33 7 A. I believe that's correct.

16:37:34 8 Q. And they would have more knowledge than
16:37:36 9 anyone at 3M surrounding maintaining normothermia and
16:37:42 10 its effects.

16:37:43 11 MR. GOSS: Object to the form of the
16:37:44 12 question.

16:37:44 13 A. Probably.

16:37:45 14 Q. Okay. So sitting here today as the 3M
16:37:47 15 representative, you are unaware of any discussions
16:37:50 16 with Andrea Kurz and Daniel Sessler regarding the
16:37:54 17 reliability of the 1996 Kurz study.

16:37:59 18 A. I've -- I've attended discussions with them
16:38:02 19 where the point was made that the -- the studies
16:38:07 20 themselves were reliable but that the temperature
16:38:10 21 differences observed in modern surgeries are much --
16:38:15 22 much higher now, that -- that patients are never
16:38:19 23 allowed to become as cold as they were allowed to
16:38:21 24 become when those studies were conducted.

16:38:23 25 Q. You analyzed the 1996 Kurz study; correct?

16:38:26 1 A. Yes.

16:38:28 2 Q. 3M has analyzed it and has extensive
16:38:31 3 knowledge of that study; correct?

16:38:32 4 A. Yes.

16:38:32 5 Q. And you would agree with me that forced --
16:38:36 6 the Bair Hugger unit, when turned on ambient, cools
16:38:39 7 the patient down; correct?

16:38:40 8 A. They -- they may do that, depending on what
16:38:45 9 the ambient temperature is.

16:38:46 10 Q. In the operating room, would you agree with
16:38:49 11 me if you turn the forced-air warming unit on, it's
16:38:53 12 most likely going to cool the patient?

16:38:56 13 A. Yes.

16:38:56 14 Q. Okay. And you guys market as --

16:38:56 15 Or that's one of the indications for use, is
16:38:59 16 for cooling patients.

16:38:59 17 A. It can be used for that purpose.

16:39:01 18 Q. And you are aware or 3M is aware that in the
16:39:04 19 1996 study, that the patients were cooled for the
16:39:11 20 control group.

16:39:12 21 A. Well, and they were warmed for the treatment
16:39:14 22 group.

16:39:14 23 Q. But they were also cooled for the control
16:39:17 24 group, and that's why they got their temperatures down
16:39:19 25 so low.

16:39:20 1 A. Yes. It's one reason, yes.

16:39:22 2 Q. Well, have you ever seen a study --

16:39:27 3 Is 3M aware of any study where, if you just
16:39:29 4 cover someone with blankets, that their core body
16:39:33 5 temperature can get below 35 degrees?

16:39:35 6 A. Yes, I believe there are several studies
16:39:37 7 that show the effect of redistribution on patients
16:39:40 8 after induction that get temperatures that low with
16:39:42 9 only blankets on them.

16:39:43 10 Q. Below 35.

16:39:44 11 A. Yeah. I think there are several early
16:39:47 12 studies from the 1990s where patients, right after
16:39:52 13 induction --

16:39:56 14 Redistribution causes a -- a decrease in
16:39:59 15 core body temperature that has nothing to do with heat
16:40:02 16 loss, and so for the first -- for the first hour
16:40:06 17 redistribution dominates the thermal status of
16:40:10 18 patients, and so they get very cold even though their
16:40:12 19 heat-loss rates don't change very much at all. And
16:40:15 20 this remains true for maybe three, four hours in most
16:40:19 21 patients.

16:40:19 22 Q. I understand that. But that usually drops
16:40:22 23 them down to 35 or something, according to the Sun
16:40:25 24 study; correct?

16:40:26 25 A. It --

16:40:26 1 Yeah, it can.

16:40:26 2 Q. Well the Sun study indicates that the drop
16:40:28 3 in temperature, whether you used forced-air warming or
16:40:31 4 blankets, is almost identical during the perioperative
16:40:34 5 period.

16:40:34 6 A. During the first hour.

16:40:35 7 Q. Yeah. Okay.

16:40:37 8 A. And -- and we would agree that
16:40:39 9 redistribution is the dominant cause of hypothermia,
16:40:44 10 at least for the first hour, and probably for the
16:40:46 11 first three.

16:40:46 12 Q. First three hours.

16:40:47 13 A. Yeah.

16:40:50 14 Q. But in today's medicine and the medicine for
16:40:57 15 the past six or seven years, a patient is very
16:41:01 16 unlikely to be cooled with a forced-air warming unit;
16:41:06 17 correct?

16:41:06 18 A. Correct.

16:41:06 19 Q. That -- that is --

16:41:08 20 That would not be used as a control group in
16:41:12 21 today's studies of normothermia.

16:41:14 22 A. Well in fact since that particular study
16:41:16 23 that you mentioned was conducted, it would be
16:41:18 24 unethical to do that.

16:41:20 25 Q. Okay.

16:41:21 1 A. No IRB would approve that in the U.S.

16:41:26 2 Q. Do you believe it was unethical in 1996?

16:41:28 3 A. No, because no one knew then.

16:41:38 4 Q. And you agree with me because it's unethical
16:41:41 5 and it doesn't happen and shouldn't happen, that using
16:41:46 6 that as a control group in the 1996 Kurz study would
16:41:51 7 not be realistic about what really occurs in an
16:41:56 8 operating room.

16:41:56 9 MR. BLACKWELL: Object to the form of the
16:41:57 10 question.

16:41:57 11 A. Well which part? Are you --

16:42:00 12 Q. The cooling of patients.

16:42:02 13 A. Well in general patients are -- are not
16:42:05 14 actively cooled in operating rooms today unless
16:42:09 15 they're having neurosurgical or cardiovascular
16:42:17 16 procedures.

16:42:52 17 Q. Are you aware, back in March of 2016, that
16:42:59 18 Sessler indicated, knowing what they know now, they
16:43:03 19 would have never published such a small study of the
16:43:05 20 1996 Kurz study?

16:43:07 21 MR. BLACKWELL: I object to the form of the
16:43:08 22 question.

16:43:09 23 A. I may have -- I may have heard Dan -- Dr.
16:43:13 24 Sessler say that.

16:43:13 25 Q. Okay.

16:43:15 1 A. But that's true of a large number of studies
16:43:18 2 that were conducted in 1996.

16:43:26 3 Q. Was 3M aware that Dr. Kurz informed them
16:43:36 4 that the 1996 colorectal study only applies to
16:43:44 5 colorectal patients and you can't extrapolate that
16:43:47 6 study to all surgeries?

16:43:49 7 MR. BLACKWELL: I object to the form of the
16:43:50 8 question, foundation.

16:43:51 9 A. We're not aware of --

16:43:52 10 I'm not aware of that.

16:43:53 11 Q. 3M is aware of the flaws of the Kurz study;
16:44:39 12 correct?

16:44:39 13 MR. BLACKWELL: I object to the form of the
16:44:40 14 question, asked and answered.

16:44:44 15 A. Well it's a study conducted in 1995, I
16:44:48 16 believe. There are some limitations that probably
16:44:52 17 wouldn't be repeated nowadays if -- if the study was
16:44:56 18 going to be repeated.

16:44:57 19 Q. Well you couldn't do the study today because
16:44:59 20 it would be unethical; correct?

16:45:01 21 A. Most likely no IRB would approve a study
16:45:05 22 like that.

16:45:05 23 Q. So small sample size; correct?

16:45:06 24 A. Well, relatively, yes.

16:45:07 25 Q. Okay. And the fact that Dr. Kurz has

16:45:12 1 indicated that the study's no longer scientifically
16:45:15 2 reliable is also a serious -- serious -- serious flaw
16:45:19 3 of the study; correct?

16:45:19 4 MR. BLACKWELL: I object to the form of the
16:45:20 5 question, foundation. Counsel is testifying.

16:45:23 6 A. I don't know that she's indicated that the
16:45:24 7 study is not reliable.

16:45:27 8 Q. If she has testified that the Kurz study is
16:45:32 9 no longer reliable in today's scientific standards,
16:45:34 10 would you disagree with her testimony?

16:45:36 11 MR. BLACKWELL: I object to the form of the
16:45:38 12 question, improper hypothetical.

16:45:39 13 A. I'd have to look at the context of that
16:45:42 14 statement. I'm not aware of her saying that, though.

16:45:46 15 Q. Well you were aware earlier, about six
16:45:52 16 questions ago, that you've heard of somebody saying
16:45:55 17 that the 1996 study would not be publishable today.

16:45:58 18 A. Because of the small sample size.

16:46:00 19 Q. Okay.

16:46:06 20 A. Not to mention the fact that it would be
16:46:08 21 unethical to conduct nowadays.

16:46:10 22 Q. And in fact, 3M is currently doing a study
16:46:20 23 out in China regarding the effects of normother -- of
16:46:25 24 maintaining normothermia or hypothermia on cardiac
16:46:30 25 events as well as infection rates.

16:46:31 1 A. Infections are a secondary outcome of that
16:46:33 2 study. Cardiovascular events are the primary outcome
16:46:35 3 of that study.

16:46:36 4 Q. So my statement was correct. I said both
16:46:40 5 cardiovascular and infection.

16:46:40 6 A. Well I'm just pointing out that the study is
16:46:44 7 powered to look at cardiovascular effects, not
16:46:46 8 surgical-site infection.

16:46:48 9 Q. Because according to -- because 3M is --
16:46:51 10 3M is aware that, according to Dr. Sessler
16:46:52 11 and Dr. Kurz, there's no reliable scientific evidence
16:46:56 12 to support the former SCIP-10 protocols; correct?

16:47:00 13 MR. BLACKWELL: I object to the form of the
16:47:01 14 question, foundation.

16:47:03 15 A. I'm -- we're not --

16:47:05 16 I'm not aware of them saying that.

16:47:10 17 Q. Okay. But if they did say that, you
16:47:12 18 wouldn't disagree with that. Fair -- fair assessment;
16:47:15 19 correct?

16:47:15 20 MR. BLACKWELL: I object to the form of the
16:47:16 21 question, improper hypothetical.

16:47:18 22 A. I'd have a discussion about it.

16:47:21 23 Q. Well --

16:47:21 24 A. It's a SCIP -- SCIP-10 --

16:47:21 25 MR. BLACKWELL: Just -- just a second.

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16:47:22 1 Object to the form of the question, also calling for
16:47:24 2 speculation.

16:47:24 3 Q. 3M has hired Andrea Kurz and Daniel Sessler
16:47:30 4 on their scientific advisory board to provide advice
16:47:34 5 regarding the effects of hypothermia; correct?

16:47:38 6 Among other things.

16:47:39 7 A. Among other things.

16:47:40 8 Q. Okay. But that's one of the reasons; --

16:47:42 9 A. Yes.

16:47:42 10 Q. -- correct?

16:47:43 11 And they hired them because they're the
16:47:45 12 leading scientists in the field; correct?

16:47:46 13 MR. BLACKWELL: I object as asked and
16:47:47 14 answered.

16:47:48 15 A. Yes.

16:47:49 16 Q. Therefore, you would -- you would defer to
16:47:53 17 Dr. Sessler and Dr. Kurz with respect to their own
16:47:57 18 studies and their own conclusions; correct?

16:47:59 19 MR. BLACKWELL: I object to the form of the
16:48:00 20 question.

16:48:02 21 A. I would give it strong weight. I'm not sure
16:48:06 22 that I would agree with that assessment, though.

16:48:08 23 Q. So you would disagree with Dr. Sessler or
16:48:12 24 Dr. Kurz with respect to maintaining normothermia and
16:48:16 25 the effects of hypothermia.

16:48:17 1 MR. BLACKWELL: Object to the form of the
16:48:20 2 question.

16:48:20 3 A. Under the -- under the conditions that
16:48:22 4 existed when they conducted the studies, I -- I think
16:48:25 5 those studies are reliable.

16:48:26 6 Q. Well science changes over years; correct?

16:48:32 7 A. Science -- science doesn't change, but
16:48:34 8 the -- the data certainly do.

16:48:36 9 Q. Well science and its interpretation of
16:48:41 10 data -- withdraw that.

16:48:43 11 You mentioned earlier, talking about
16:48:45 12 particle counts, that new evidence shows that particle
16:48:49 13 counts may have no effect on surgical-site infections,
16:48:55 14 basically eliminating the studies done on laminar flow
16:48:58 15 back in the day by Lidell; correct?

16:49:00 16 MR. BLACKWELL: Object to the form of the
16:49:01 17 question.

16:49:02 18 A. Done by --

16:49:02 19 Q. Lidell, L-i-d-e-l-l.

16:49:05 20 A. I didn't even refer to those studies. I
16:49:09 21 wasn't talking about those particular studies.

16:49:09 22 Q. Well you were referring to current studies
16:49:11 23 that have looked retrospectively at laminar flow
16:49:14 24 systems and whether or not they reduced particle
16:49:17 25 counts and whether or not they have an effect on

16:49:18 1 surgical-site infections.

16:49:20 2 A. They actually, I don't believe, looked at
16:49:22 3 particle counts, they simply looked at surgical-site
16:49:26 4 infections under the conditions of laminar airflow
16:49:27 5 and/or surgical exhaust suits.

16:49:31 6 Q. And that's what you were referring to when
16:49:33 7 we had that discussion previously; correct?

16:49:34 8 A. Yes.

16:49:34 9 Q. Okay. But 20 years ago the science was that
16:49:39 10 laminar flow and the surgical hoods helped reduce
16:49:42 11 surgical-site infections; correct?

16:49:44 12 A. No. That's always been controversial. And
16:49:47 13 in fact, one of the reasons that it hasn't been
16:49:49 14 adopted in the United States was the existing
16:49:52 15 controversy about whether it was effective or not.

16:50:22 16 Q. You were aware that recent studies indicate
16:50:35 17 that maintaining normothermia has no effect on
16:50:38 18 surgical-site infections.

16:50:39 19 MR. BLACKWELL: I object as asked and
16:50:40 20 answered.

16:50:43 21 A. I'm aware of -- of retrospective studies
16:50:46 22 that show that normothermia -- or that the warming
16:50:55 23 in -- warming in a group of patients compared to
16:50:58 24 patients who are not warmed have similar rates of
16:51:02 25 surgical-site infection.

16:51:04 1 Q. And I believe that's the --

16:51:07 2 Is that the Brown study?

16:51:08 3 A. There are many of them, but Brown is one.

16:51:10 4 Q. And the --

16:51:10 5 A. Scott is another.

16:51:11 6 Q. And the Brown study was done from data from

16:51:15 7 Johns Hopkins University; correct?

16:51:16 8 A. No. I believe Brown was done from Mayo.

16:51:18 9 Q. Okay.

16:51:19 10 A. Scott was done from Johns Hopkins.

16:51:22 11 Q. You're right. Correct. And they both

16:51:24 12 showed the same thing, that there's no evidence

16:51:26 13 supporting that maintaining normothermia reduces the

16:51:29 14 incidence of surgical-site infection; correct?

16:51:31 15 A. In very-low-risk patients.

16:51:34 16 Q. Well do you think --

16:51:35 17 A. And that's an important -- I mean that's an

16:51:37 18 important difference in the -- in the -- in the

16:51:40 19 papers. For example, from Kurz and -- and Steve

16:51:43 20 Frank, those patients were very-high-risk patients,

16:51:47 21 and of course they, both of those papers, randomized

16:51:53 22 controlled trials, showed large differences in

16:51:55 23 outcomes in patients who are at high risk. The

16:51:59 24 studies that you refer to, Brown and Scott, are

16:52:02 25 conducted in patients who are very low risk of getting

16:52:05 1 a surgical-site infection. So it's not entirely
16:52:09 2 surprising that they don't show differences.

16:52:11 3 However, the Scott paper showed profound
16:52:16 4 differences in healthcare-acquired infections. If you
16:52:21 5 look at the composite score, they also show
16:52:23 6 differences in cardiac events and mortality in
16:52:25 7 patients who were warmed compared to patients who were
16:52:28 8 not warmed.

16:52:29 9 Q. You agree that Dr. Sessler says that the
16:52:31 10 evidence on the cardiac events are very weak and
16:52:35 11 unreliable in the -- in the Scott study.

16:52:38 12 MR. BLACKWELL: I object to the form of the
16:52:39 13 question.

16:52:39 14 A. I'm not aware of that.

16:52:40 15 Q. Okay. Would you consider total hip and
16:52:47 16 total knee high risk or low risk?

16:52:50 17 A. Very low risk.

16:52:58 18 Q. [REDACTED]

16:53:02 19 [REDACTED]

16:53:08 20 [REDACTED]

16:53:11 21 [REDACTED]

16:53:13 22 [REDACTED] [REDACTED]

16:53:14 23 [REDACTED]

16:53:15 24 [REDACTED] [REDACTED]

16:53:16 25 [REDACTED]

			276
16:53:19	1		
16:53:24	2		
16:53:28	3		
16:53:31	4		
16:53:36	5		
16:53:38	6		
16:53:46	7		
16:53:53	8		
16:54:29	9		
16:54:31	10		
16:54:33	11		
16:54:35	12		
16:54:40	13		
16:54:42	14		
16:54:44	15		
16:54:44	16		
16:54:47	17		
16:54:51	18		
16:56:23	19		
16:56:27	20		
16:56:28	21		
16:56:35	22		
16:56:42	23		
16:56:46	24		
16:56:49	25		

16:56:49 1 Q. [REDACTED]

16:56:52 2 [REDACTED] [REDACTED] [REDACTED]

16:56:53 3 [REDACTED] [REDACTED]

16:56:55 4 [REDACTED] [REDACTED]

16:56:55 5 [REDACTED] [REDACTED]

16:56:58 6 [REDACTED] [REDACTED]

16:57:05 7 [REDACTED] .

16:57:08 8 Q. And Michelle Stevens is the medical

16:57:10 9 director; correct?

16:57:10 10 A. Yes.

16:57:11 11 Q. And Gary Hansen had a -- had a high position

16:57:13 12 at that time; correct?

16:57:14 13 A. Yes.

16:57:14 14 Q. And Mark Scott was director of marketing.

16:57:17 15 A. Yes.

16:57:18 16 Q. Okay. And you were director of clinical

16:57:19 17 affairs; correct?

16:57:20 18 A. In 2012. No, I was not.

16:57:22 19 Q. What was your title?

16:57:24 20 A. I was a senior research associate.

16:57:30 21 Q. [REDACTED]

16:57:32 22 [REDACTED]

16:57:35 23 [REDACTED]

16:57:37 24 [REDACTED] [REDACTED]

16:57:38 25 [REDACTED]

				279
16:58:25	1	■	■	■
16:58:27	2	■		
16:58:27	3	■	■	
16:58:28	4		■	
16:58:29	5	■	■	
16:58:32	6	■	■	■
16:58:32	7	■	■	
16:58:34	8	■	■	
16:58:39	9	■	■	
16:58:42	10	■	■	
16:58:44	11	■	■	
16:58:46	12	■	■	
16:58:48	13		■	■
16:58:49	14	■		
16:58:50	15	■	■	
16:58:54	16	■		
16:58:55	17	■	■	
16:58:58	18	■	■	
16:58:59	19	■	■	
16:59:00	20	■	■	
16:59:05	21	■	■	
16:59:08	22		■	■
16:59:10	23	■		
16:59:10	24	■	■	
16:59:10	25	■	■	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

			280
16:59:14	1	[REDACTED]	
16:59:17	2	[REDACTED]	
16:59:31	3	[REDACTED] [REDACTED]	
16:59:34	4	[REDACTED]	
16:59:38	5	[REDACTED]	
16:59:41	6	[REDACTED]	
16:59:43	7	[REDACTED] [REDACTED]	
16:59:45	8	[REDACTED]	
16:59:47	9	[REDACTED]	
16:59:48	10	[REDACTED] [REDACTED]	
16:59:48	11	[REDACTED] [REDACTED]	
16:59:51	12	[REDACTED] [REDACTED]	
16:59:55	13	[REDACTED]	
16:59:57	14	[REDACTED]	
17:00:01	15	[REDACTED] [REDACTED]	
17:00:03	16	[REDACTED]	
17:00:04	17	[REDACTED] [REDACTED]	
17:00:04	18	[REDACTED] [REDACTED] [REDACTED]	
17:00:07	19	[REDACTED]	
17:00:14	20	[REDACTED]	
17:00:19	21	[REDACTED]	
17:00:20	22	[REDACTED] [REDACTED]	
17:00:21	23	[REDACTED]	
17:00:21	24	[REDACTED] [REDACTED]	
17:00:27	25	[REDACTED]	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

			281
17:00:32	1	[REDACTED]	[REDACTED]
17:00:36	2	[REDACTED]	[REDACTED]
17:00:36	3	[REDACTED]	[REDACTED]
17:00:38	4	[REDACTED]	[REDACTED]
17:00:41	5	[REDACTED]	[REDACTED]
17:00:43	6	[REDACTED]	[REDACTED]
17:00:46	7	[REDACTED]	[REDACTED]
17:00:49	8	[REDACTED]	[REDACTED]
17:00:51	9	[REDACTED]	[REDACTED]
17:00:53	10	[REDACTED]	[REDACTED]
17:00:56	11	[REDACTED]	[REDACTED]
	12	[REDACTED]	[REDACTED]
17:00:56	13	[REDACTED]	[REDACTED]
17:00:56	14	[REDACTED]	[REDACTED]
17:00:57	15	[REDACTED]	[REDACTED]
17:00:59	16	[REDACTED]	[REDACTED]
17:01:01	17	[REDACTED]	[REDACTED]
17:01:03	18	[REDACTED]	[REDACTED]
17:01:04	19	[REDACTED]	[REDACTED]
17:01:06	20	[REDACTED]	[REDACTED]
	21	[REDACTED]	[REDACTED]
17:01:07	22	[REDACTED]	[REDACTED]
17:01:08	23	[REDACTED]	[REDACTED]
17:01:09	24	[REDACTED]	[REDACTED]
17:01:11	25	[REDACTED]	[REDACTED]

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17:02:21 1 [REDACTED]

17:02:28 2 [REDACTED] [REDACTED]

17:02:33 3 [REDACTED]

17:02:35 4 [REDACTED] [REDACTED]

17:02:35 5 [REDACTED] [REDACTED]

17:02:38 6 [REDACTED]

17:02:38 7 [REDACTED] [REDACTED]

17:02:39 8 [REDACTED] [REDACTED]

17:02:43 9 [REDACTED] [REDACTED]

17:02:44 10 [REDACTED]

17:02:45 11 [REDACTED] [REDACTED]

17:02:47 12 [REDACTED]

17:02:48 13 [REDACTED] [REDACTED]

17:02:52 14 [REDACTED] [REDACTED]

17:02:53 15 [REDACTED] [REDACTED]

17:02:54 16 [REDACTED] [REDACTED]

17:02:56 17 Q. You -- you -- you -- you -- you stated that

17:02:58 18 all -- all studies are -- have some sort of flaws.

17:03:01 19 Are you saying this study does not have any flaws?

17:03:03 20 A. All -- all -- all clinical trials have

17:03:06 21 limitations in some way. There is no perfectly

17:03:10 22 conducted trial, which is why we have to do many of

17:03:12 23 them.

17:03:13 24 Q. Well Zink wasn't a clinical trial; was it?

17:03:15 25 A. It was a --

17:03:16 1 No, it was not.

17:03:17 2 Q. Okay. Zink only had eight people; correct?

17:03:22 3 A. Volunteers.

17:03:24 4 Q. Yeah.

17:03:24 5 A. Yes.

17:03:24 6 Q. Volunteers.

17:03:26 7 And the data from Zink is inconclusive;

17:03:37 8 correct?

17:03:37 9 A. It doesn't -- it doesn't assert that there

17:03:40 10 is greater infect -- contamination risk with or

17:03:45 11 without.

17:03:47 12 Q. And Zink was in 1991; correct?

17:03:50 13 A. I believe that's correct.

17:03:51 14 Q. Well let me just be sure.

17:03:55 15 A. It's a very early one.

17:03:57 16 Q. It was accepted for publication in 1992 and

17:04:00 17 published in 1993. I'm sorry.

17:04:01 18 A. Okay.

17:04:02 19 Q. Do you know what Bair Hugger unit was used

17:04:04 20 in Zink?

17:04:05 21 A. I believe it was a -- a model 500.

17:04:09 22 Q. Okay. And you agree with me that the model

17:04:23 23 500 that was used was put on the medium setting, not

17:04:26 24 the high setting for temperature.

17:04:28 25 A. I seem to recall that that was one of the

17:04:32 1 settings in the study.

17:04:33 2 Q. So sitting here today, we don't know whether
17:04:37 3 or not, based on Zink, whether or not putting the 500
17:04:41 4 on the high temperature, which would have been 43
17:04:44 5 degrees Celsius, would have had an effect on the data
17:04:47 6 provided by Zink; correct?

17:04:50 7 A. Today we do not know that.

17:04:51 8 Q. Okay. And the medium temperature is at 38
17:04:55 9 degrees, correct, --

17:04:55 10 A. Yes.

17:04:56 11 Q. -- plus or minus three degrees Celsius;
17:04:58 12 correct?

17:04:58 13 A. At that time, yes.

17:05:01 14 Q. Because of the controls and the sensor;
17:05:02 15 correct?

17:05:02 16 A. There's no end-of-hose sensor --

17 17 Q. Yes.

17:05:03 18 A. -- on the 500.

17:05:04 19 Q. And because of that, also -- strike that.

17:05:09 20 There's no mention in Zink that the Bair
17:05:15 21 Hugger unit was tested and calibrated properly prior
17:05:19 22 to testing; correct?

17:05:21 23 A. That's not indicated.

17:05:22 24 Q. Okay. And therefore, we don't know whether
17:05:26 25 or not the temperature coming out of the Bair Hugger

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17:05:27 1 unit is 38 degrees, 42 degrees, 32 degrees, we just
17:05:34 2 don't know because of the margin of error.

17:05:40 3 A. We don't know.

17:05:41 4 Q. Okay. And that's a significant flaw in the
17:05:45 5 study.

17:05:50 6 A. It's a -- it's a limitation. The -- the
17:05:53 7 temper --

17:05:53 8 It would have been great to have the
17:05:55 9 temperature measured and cal -- and the unit
17:05:58 10 calibrated and reported.

17:05:59 11 Q. Well I mean do you agree with me that
17:06:01 12 temperature -- that the change in the temperature
17:06:04 13 coming out of a Bair Hugger unit may have an effect on
17:06:10 14 disruption of the sterile field?

17:06:12 15 A. It may.

17:06:13 16 Q. Okay. And the higher the temperature, the
17:06:16 17 bigger -- the higher the chance that it could disrupt
17:06:18 18 the -- the sterile field.

17:06:20 19 A. It's a possibility.

17:06:21 20 Q. Because temperature is heat, and heat has
17:06:24 21 energy; correct?

17:06:25 22 A. Yes.

17:06:26 23 Q. And energy could cause thermal plumes;
17:06:29 24 correct?

17:06:29 25 A. It could.

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17:06:30 1 Q. Okay. And thermal plumes cause turbulence;
17:06:34 2 correct?

17:06:34 3 A. They're --

17:06:36 4 If they're strong enough, yes.

17:06:38 5 Q. And actually, you saw in the Schlieren
17:06:40 6 models that you did that -- you saw the density above
17:06:42 7 the Bair Hugger unit differed as a result of the heat.

17:06:48 8 A. And -- and also the conductive warming
17:06:51 9 blankets as well.

17:06:52 10 Q. Yeah. But with respect to the disruption of
17:07:02 11 the airflow, you would agree with me, based on a Kurz
17:07:05 12 study comparing PerfectTemp to the Bair Hugger, that
17:07:09 13 the change in temperature above the operating room
17:07:11 14 table was much higher when the Bair Hugger was used as
17:07:17 15 compared to the PerfectTemp device; correct?

17:07:18 16 A. Yes.

17:07:18 17 Q. Okay. You're aware that the Bair Hugger
17:07:21 18 produces more waste heat than the conductive warming
17:07:24 19 PerfectTemp in that study.

17:07:26 20 A. I'm not aware that it produces more waste
17:07:28 21 heat, but the temperature of the air above it is
17:07:31 22 higher.

17:07:31 23 Q. Okay. Significantly higher.

17:07:34 24 MR. BLACKWELL: Object to the form of the
17:07:35 25 question.

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17:07:35 1 Q. I mean the p-value was below .05 in that --
17:07:39 2 in that testing.

17:07:40 3 A. Yes.

17:07:41 4 Q. Okay. So it was a statistical significant
17:07:43 5 result that the Bair Hugger produced more heat above
17:07:46 6 the operating room table than the PerfectTemp in -- in
17:07:49 7 a study conducted by Andrea Kurz; correct?

17:07:51 8 A. It produced higher temperatures.

17:07:53 9 Q. Yeah. Correct?

17:07:54 10 A. Yes.

17:08:01 11 Q. Finally, Hall and --
17:08:05 12 Is it Teenier or Teerier?

17:08:07 13 A. Teenier.

17:08:09 14 Q. Teenier. That's another study that 3M has
17:08:14 15 knowledge and has analyzed and has cited to in -- in
17:08:21 16 its documents; correct?

17:08:22 17 A. In the -- in the past we have, yes.

17:08:23 18 Q. And that was a December 9th --
17:08:25 19 It was a poster presentation on December
17:08:28 20 9th, 1991; correct?

17:08:29 21 A. At the PGA, yes.

17:08:32 22 Q. Okay. And do you know what device, Bair
17:08:34 23 Hugger device was used in that study?

17:08:35 24 A. I don't know.

17:08:36 25 Q. It definitely wasn't the 505; correct?

17:08:38 1 A. It couldn't have been in 1991.

17:08:40 2 Q. Okay. It was the 500 around 1991.

17:08:43 3 A. Yes.

17:08:43 4 Q. But it could have been the 275 or --

17:08:45 5 We don't know.

17:08:46 6 A. It -- it could have been.

17:08:46 7 Q. Okay.

17:08:49 8 A. More likely not.

17:08:49 9 Q. And you agree with me that this is an

17:08:52 10 unpublished study.

17:08:53 11 A. It's un -- it --

17:08:55 12 Well it was -- it was published at the PGA.

17:08:57 13 Q. As a poster.

17:08:58 14 A. Yes.

17:08:59 15 Q. Not peer reviewed.

17:09:00 16 A. No.

17:09:00 17 Q. And in the scientific world, if it's not

17:09:03 18 peer reviewed, it's really not a reliable study.

17:09:07 19 A. It has less -- less compelling status than a

17:09:12 20 peer-reviewed study, yes.

17:09:13 21 Q. I mean it has a very low compelling status

17:09:17 22 compared to a peer-reviewed study.

17:09:19 23 A. In general.

17:09:19 24 Q. Okay. Because it hasn't been peer-reviewed,

17:09:22 25 hasn't been tested by other people in the field.

17:09:24 1 MR. BLACKWELL: Object as asked and
17:09:27 2 answered.

17:09:27 3 A. That's correct. Generally, they're a
17:09:29 4 prelude to a published -- published article though.

17:09:31 5 Q. But there was no prelude to a published
17:09:34 6 article. There wasn't a published article from this
17:09:37 7 study; correct?

17:09:37 8 A. Not that we're aware of.

17:09:39 9 Q. Okay. Was this study funded by Augustine
17:09:41 10 Medical?

17:09:41 11 A. I believe it was.

17:09:42 12 Q. Okay. So you rely -- I mean the --

17:09:48 13 The studies that 3M relies upon regarding
17:09:52 14 contamination are studies that were funded by Scott
17:09:55 15 Augustine, such as Zink, Hall and Teenier; correct?

17:10:00 16 A. Well --

17:10:01 17 Q. He -- he funded those studies; correct?

17:10:03 18 A. Well Augustine Medical funded those studies,
17:10:06 19 yes, --

17:10:06 20 Q. And --

17:10:07 21 A. -- when Scott Augustine was there.

17:10:10 22 Q. Okay. You mentioned many of the flaws in
17:10:48 23 the studies that 3M has knowledge and analyzed, such
17:10:53 24 as Sessler, Kurz, Zink, Huang. Every study has flaws;
17:11:01 25 correct?

17:11:01 1 A. Limitations.

17:11:02 2 Q. Limitations, flaws.

17:11:04 3 Based on this analysis and knowledge, has 3M
17:11:19 4 publicized these limitations of these studies of Zink
17:11:26 5 and Kurz and Huang and Avidan to the public, to the
17:11:35 6 consumers?

17:11:36 7 MR. BLACKWELL: Object to the question as
17:11:37 8 beyond the scope of the 30(b)(6) designation.

17:11:41 9 A. No, we have not.

17:12:10 10 Q. Switching subjects, you would agree that the
17:12:16 11 studies of third-party testing indicate that the Bair
17:12:22 12 Hugger unit harbors bacteria inside the device.

17:12:26 13 A. Well I would -- I would agree that bacteria
17:12:29 14 can be recovered from the interior of the device.

17:12:31 15 Q. Because the device is not sterile.

17:12:34 16 A. It's not sterile.

17:12:34 17 Q. And in fact, you're not -- 3M is not
17:12:41 18 disputing that the Bair Hugger blower and hose can
17:12:47 19 harbor bacteria inside the device.

17:12:50 20 A. We are not disputing that.

17:12:51 21 Q. Okay.

17:12:52 22 A. It's not sterile.

17:12:53 23 Q. Okay.

17:12:59 24 MR. ASSAAD: Take a five-minute break.

17:13:00 25 THE REPORTER: Off the record, please.

17:26:07 1 (Recess taken.)

17:26:07 2 BY MS. ZIMMERMAN:

17:26:11 3 Q. Good afternoon, Mr. Van Duren. My name is
17:26:13 4 Genevieve Zimmerman and I'm one of the attorneys
17:26:15 5 representing the plaintiffs in this matter. I'm here
17:26:17 6 to take some deposition testimony from you or from 3M
17:26:21 7 with respect to three of the topics noticed in the
17:26:24 8 deposition notice, --

17:26:25 9 A. Okay.

17:26:26 10 Q. -- specifically numbers four, eight and 12.

17:26:32 11 To start with, if you don't understand
17:26:34 12 something that I ask, please let me know and I'll do
17:26:37 13 my best to reformulate the question. All right?

17:26:39 14 A. Okay.

17:26:39 15 Q. All right. And if -- if you do answer a
17:26:41 16 question, I'm going to understand and assume that you
17:26:44 17 understood it. Is that fair?

17:26:45 18 A. Yes.

17:26:46 19 Q. Okay. And you understand that you've been
17:26:48 20 designated to speak on behalf of the defendants in
17:26:51 21 this matter?

17:26:51 22 A. Yes.

17:26:51 23 Q. And that you have prepared -- you are
17:26:54 24 prepared as you sit here today to answer questions
17:26:57 25 with respect to topics number four, eight and 12; is

17:27:00 1 that right?

17:27:00 2 MR. BLACKWELL: Can I show him four, eight
17:27:03 3 and 12 so he can see it?

17:27:05 4 MS. ZIMMERMAN: You sure can, Jerry.

17:27:07 5 Q. So number four is decisions relating to the
17:27:11 6 labeling and warnings, and then in brackets it says
17:27:13 7 non-regulatory, end brackets, for the Bair Hugger 700
17:27:17 8 series and 500 series products allegedly used in
17:27:20 9 plaintiffs' surgeries at issue in this litigation.

17:27:24 10 A. Yes.

17:27:24 11 Q. All right. Number eight says data or
17:27:27 12 research supporting the claim that Bair Hugger
17:27:29 13 blankets act as an additional filter or otherwise
17:27:32 14 reduce the potential for contamination in the
17:27:34 15 operating room. And then number 12, the purpose,
17:27:37 16 activities, conclusions reached, and outcome of,
17:27:41 17 quote, Project Volcano, end quote.

17:27:44 18 Did I read those correctly?

17:27:45 19 A. Yes.

17:27:45 20 Q. And you are indeed prepared to answer
17:27:47 21 questions with respect to those three topics today?

17:27:50 22 A. Yes.

17:27:50 23 Q. All right. And you are aware that the
17:27:53 24 answers that you give today are going to be binding
17:27:56 25 upon the defendant; is that right?

17:27:57 1 A. Yes.

17:27:57 2 Q. Okay. Did you meet with people --

17:28:01 3 Who did you meet with to prepare for your
17:28:05 4 answers in your deposition today?

17:28:09 5 A. With Peter Goss and a -- a -- a couple of
17:28:19 6 other attorneys at Blackwell Burke, Debra and
17:28:23 7 Charlene.

17:28:23 8 Q. All right. And did you -- did you review
17:28:26 9 documents in preparation for your testimony on these
17:28:29 10 topics as well?

17:28:30 11 A. Yes.

17:28:30 12 Q. And did you bring any of those documents
17:28:33 13 with you here today?

17:28:33 14 A. No, I did not.

17:28:34 15 Q. All right. And why is that?

17:28:36 16 MR. BLACKWELL: Object as asked and
17:28:36 17 answered.

17:28:37 18 A. I never bring documents to a deposition.

17:28:39 19 Q. Okay. Have you been instructed not to bring
17:28:41 20 documents to depositions?

17:28:42 21 A. No.

17:28:44 22 Q. All right. With respect to topic number
17:28:49 23 four, which is decisions relating to labeling and
17:28:52 24 warnings, would you agree that the labeling and
17:28:55 25 warnings are ultimately given to the user of this

17:28:58 1 device?

17:28:58 2 A. Yes.

17:28:59 3 Q. All right. And would you agree that it's
17:29:02 4 fair to say labeling and warnings are essentially the
17:29:05 5 rules for using the machine?

17:29:08 6 A. Yes.

17:29:09 7 Q. You would agree that following rules is
17:29:12 8 important.

17:29:12 9 A. Yes.

17:29:13 10 Q. And -- and it's important because you need
17:29:15 11 to keep the patient safe; correct?

17:29:17 12 A. Yes.

17:29:18 13 Q. And -- and in fact keeping the patient safe
17:29:22 14 is going to be the most important goal for any medical
17:29:24 15 device company; right?

17:29:26 16 A. Safety is a -- a very important goal for
17:29:32 17 medical devices. It may not be the primary goal.

17:29:35 18 Q. As you sit here today, can you think of a
17:29:37 19 goal that is more important to the company than
17:29:40 20 keeping the patient safe?

17:29:41 21 A. I mean there are many medical devices that
17:29:43 22 are -- that have very, very high risks, but they're
17:29:46 23 used on patients who are -- without the -- without the
17:29:51 24 intervention, would die, and so the -- the risks that
17:29:55 25 are tolerable of devices like that are very, very

17:29:59 1 high. Like kidney dialysis for acute renal failure,
17:30:05 2 for example, those devices have very high risk, but a
17:30:08 3 hundred percent of those patients who don't get those
17:30:10 4 devices would die.

17:30:11 5 Q. Right. But the goal for whatever medical
17:30:13 6 device company manufactures a device is always to keep
17:30:16 7 the patient safe; correct?

17:30:17 8 A. As safe as possible.

17:30:19 9 Q. All right. And that is a goal that 3M
17:30:20 10 shares; correct?

17:30:21 11 A. Yes.

17:30:21 12 Q. And to that end 3M has an obligation to
17:30:24 13 provide accurate rules for use of its machine; right?

17:30:28 14 MR. BLACKWELL: I object to the form of the
17:30:29 15 question.

17:30:31 16 A. Well we're required to put labeling on our
17:30:34 17 device that meets FDA spec -- recommend -- or
17:30:39 18 requirements.

17:30:39 19 Q. Right. And the user of the machine is going
17:30:42 20 to rely on the instructions that you provide on the
17:30:45 21 machine; correct?

17:30:45 22 A. Yes.

17:30:45 23 Q. And so it is 3M's obligation, then, to make
17:30:49 24 sure that those rules are accurate; correct?

17:30:51 25 MR. BLACKWELL: I object to the form of the

17:30:53 1 question.

17:30:53 2 A. We do our best to make the labeling as
17:30:58 3 accurate as it possibly can be.

17:31:00 4 Q. All right. And -- and you'd agree that --
17:31:03 5 that the obligation is also to make sure that those
17:31:05 6 rules or instructions are complete; correct?

17:31:06 7 A. Yes.

17:31:08 8 Q. And the rules are communicated to the end
17:31:12 9 user through the labels and warnings; correct?

17:31:14 10 A. Yes.

17:31:16 11 Q. And if the rules are not properly
17:31:19 12 communicated to the user of the machine, patients can
17:31:21 13 be harmed; correct?

17:31:24 14 A. That --

17:31:24 15 It's possible.

17:31:29 16 Q. Would you agree with me that the rules
17:31:34 17 provided to the end user need to be easy to
17:31:36 18 understand?

17:31:36 19 A. Yes.

17:31:37 20 Q. The best idea is to keep them pretty simple;
17:31:40 21 agree?

17:31:40 22 A. Yes.

17:31:41 23 Q. Keep them short if possible?

17:31:44 24 A. If it's possible, yes.

17:31:45 25 Q. Try to make them as straightforward as

17:31:47 1 possible; right?

17:31:48 2 A. Yes.

17:31:49 3 Q. And in order to provide adequate labels and
17:31:54 4 warnings, you'd agree that a company has to know where
17:31:57 5 it is the product is going to be used; right?

17:31:59 6 A. That's one of the considerations.

17:32:02 7 Q. All right. And -- and that's the
17:32:04 8 environment of use for the product; correct?

17:32:06 9 A. Yes.

17:32:07 10 Q. And so with respect to the Bair Hugger
17:32:11 11 devices that you've been designated to testify about
17:32:14 12 here today, the theater of use is known to 3M;
17:32:18 13 correct?

17:32:18 14 A. Yes.

17:32:19 15 Q. And that's the operation room; right?

17:32:21 16 A. Mostly, yes.

17:32:23 17 Q. All right. And 3M knows that operation
17:32:28 18 rooms are -- are to be as sterile as possible;
17:32:31 19 correct?

17:32:31 20 A. No.

17:32:34 21 Q. 3M does not agree that operating rooms
17:32:37 22 should be as sterile as possible?

17:32:39 23 A. Operating rooms are not sterile.

17:32:40 24 Q. Well that's a little different than my -- my
17:32:42 25 question, sir. Operating rooms may not actually be

17:32:46 1 sterile, but the goal is to have them as sterile as
17:32:48 2 possible; correct?

17:32:49 3 A. Well "sterile" is -- is really a binary
17:32:52 4 condition; either things are sterile or they're not
17:32:54 5 sterile. There's not really a -- an intermediate
17:32:59 6 sterility.

17:32:59 7 The rooms are decontaminated in between use
17:33:03 8 with either -- chemicals that inhibit the growth
17:33:07 9 of -- of -- of bacteria, and they're cleaned, so
17:33:12 10 they're --

17:33:12 11 But they're not sterile.

17:33:14 12 Q. And -- and all of this cleaning is done to
17:33:17 13 promote sterility in the operating room; is that fair?

17:33:20 14 A. It's done to reduce the bacterial load in
17:33:23 15 the operating room.

17:33:24 16 Q. All right. And you would agree that
17:33:26 17 surgeons work very hard to reduce the risk of
17:33:28 18 surgical-site infections; right?

17:33:30 19 MR. BLACKWELL: I object to the form of the
17:33:31 20 question.

17:33:33 21 A. That's certainly one of their goals.

17:33:34 22 Q. All right. And 3M is aware that the
17:33:38 23 operating room has intentionally-designed airflow that
17:33:44 24 is intended to help decrease the risk of infection;
17:33:47 25 correct?

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17:33:47 1 A. That's one of its purposes.

17:33:48 2 Q. All right. And you had some questions posed
17:33:54 3 to you earlier today, or 3M did, that -- that shows --
17:34:00 4 pardon me -- with respect to knowledge about studies
17:34:04 5 and increased particle counts. Do you recall that
17:34:06 6 line of questioning?

17:34:06 7 A. Yes.

17:34:07 8 Q. And you testified on behalf of 3M that the
17:34:10 9 company is aware that -- that studies show increased
17:34:15 10 particle count when the Bair Hugger machine is turned
17:34:17 11 to warm setting in operating rooms; correct?

17:34:19 12 MR. BLACKWELL: Object to the form of the
17:34:21 13 question.

17:34:21 14 A. Trivial increases, yes.

17:34:23 15 Q. They --

17:34:25 16 But you are aware that the studies do show
17:34:26 17 increased rate of particle count in operating rooms
17:34:29 18 with the Bair Hugger set to warm; correct?

17:34:31 19 MR. BLACKWELL: Same objection.

17:34:33 20 A. Yes.

17:34:35 21 Q. And you'd agree that increased particle
17:34:38 22 count is something that 3M has never warned orthopedic
17:34:42 23 surgeons about; correct?

17:34:43 24 A. Not to my knowledge.

17:34:47 25 Q. So my question is -- is accurate?

17:34:49 1 A. Yes.

17:34:52 2 Q. You're aware that orthopedic surgeons do in
17:34:55 3 fact care about increased particle counts; correct?

17:34:57 4 MR. BLACKWELL: I object to the form of the
17:34:58 5 question.

17:34:58 6 A. Many of them do.

17:34:59 7 Q. And in fact some of these orthopedic
17:35:02 8 surgeons have contacted the company from time to time
17:35:04 9 about these concerns; correct?

17:35:05 10 A. Yes.

17:35:08 11 Q. And the company is aware that an increase in
17:35:11 12 particle count can be associated with an increase in
17:35:14 13 bacteria load as well; correct?

17:35:15 14 A. The research regarding that is pretty
17:35:18 15 controversial. There is -- there's really not uniform
17:35:23 16 agreement about the relationship between particulates
17:35:27 17 recovered at a particular site and the subsequent
17:35:30 18 development of a surgical-site infection.

17:35:33 19 Q. Would you agree that --

17:35:35 20 Well, would 3M agree that an increase in
17:35:37 21 bacterial load can lead to infections of patients?

17:35:41 22 A. Again, the --

17:35:42 23 It's a controversial topic. There is still
17:35:46 24 no uniform agreement about the relationship between
17:35:50 25 particulates in the air, which are not bacteria but

17:35:54 1 particulates, and the subsequent development of a
17:35:57 2 surgical-site infection.

17:35:58 3 Q. All right. So does -- does 3M have a
17:36:01 4 position that increased bacterial counts in the
17:36:05 5 operating room are not associated with an increased
17:36:09 6 rate of infection?

17:36:09 7 A. Our position is that it is -- it's not a --
17:36:13 8 The science is not fixed on -- on that
17:36:16 9 question. It's still a question. It's still
17:36:19 10 controversial. No one really knows what the
17:36:21 11 relationship is between particle counts and surgical-
17:36:26 12 site infections.

17:36:26 13 Q. And what studies do you -- does 3M cite to
17:36:30 14 in support of that proposition?

17:36:32 15 A. There are a large number of studies that
17:36:34 16 have failed to show any relationship between part --
17:36:38 17 particulate counts and even CFUs and the relationship
17:36:42 18 of subsequent development of a surgical-site
17:36:45 19 infection.

17:36:45 20 Q. And which studies are you referring to?

17:36:47 21 A. Well I don't remember the exact studies. We
17:36:50 22 have numerous ones of them.

17:36:51 23 Q. Can you cite to one?

17:36:52 24 A. I can think of an NIH study by -- I'm not
17:37:01 25 sure how to pronounce the author's name -- J-o-r-g-e,

17:37:06 1 comes to mind. But there are many others.

17:37:08 2 Q. All right. So you are able to cite to

17:37:12 3 potentially one NIH study that associates -- or that

17:37:17 4 does not find a connection between increased bacterial

17:37:21 5 count and the rate of infection?

17:37:22 6 MR. BLACKWELL: I object to the form of the

17:37:23 7 question.

17:37:25 8 A. Yes.

17:37:26 9 Q. Are you able to cite to any others?

17:37:28 10 A. Not -- not sitting here, no. I don't have

17:37:31 11 my database with me, so no, I do not.

17:37:33 12 Q. All right. And -- and you prepared for the

17:37:36 13 deposition today and understood that one of -- that

17:37:39 14 the -- one of the topics identified was -- was

17:37:43 15 identifying the different kinds of third-party testing

17:37:46 16 that the company was relying on; correct?

17:37:48 17 A. Yes.

17:37:49 18 Q. But as you sit here right now, there's one

17:37:51 19 NIH study that you're able to cite to.

17:37:53 20 A. Yes.

17:38:00 21 Q. You'd agree that a known risk of knee and

17:38:06 22 hip surgery, particularly -- particularly knee and hip

17:38:11 23 replacement surgery, is surgical-site infection;

17:38:14 24 correct?

17:38:14 25 A. I'm sorry. Would you repeat the question?

17:38:16 1 Q. I'll do my best to.

17:38:18 2 You would agree that knee and hip
17:38:21 3 replacement surgery, one of the known risks is
17:38:23 4 surgical-site infection; correct?

17:38:24 5 A. Yes.

17:38:25 6 Q. All right. And you'd agree that 3M never
17:38:30 7 really evaluated the risks associated with use of Bair
17:38:33 8 Hugger in total knee or total hip surgeries; correct?

17:38:36 9 A. Not -- not specifically in that type of
17:38:39 10 surgery.

17:38:39 11 Q. All right. So you'd agree that there was
17:38:41 12 never a specific clinical trial or -- or other
17:38:44 13 evaluation that 3M or Arizant did that focused on the
17:38:48 14 use of Bair Hugger in total hip and total knee
17:38:50 15 surgeries.

17:38:53 16 A. Correct. Not to my knowledge.

17:38:56 17 Q. And you --

17:38:57 18 The company knows that there's a smaller
17:39:00 19 number of colony-forming units that are needed to
17:39:03 20 create an infection in these types of patients;
17:39:05 21 correct?

17:39:05 22 A. In implant patients.

17:39:08 23 Q. Yes.

17:39:09 24 A. Yes.

17:39:10 25 Q. And -- and that was known to the company;

17:39:13 1 correct?

17:39:13 2 A. It's known.

17:39:14 3 Q. All right. And yet 3M did advertise and --
17:39:18 4 and market the use of Bair Hugger for all kinds of
17:39:21 5 patients on things like the website; correct?

17:39:23 6 A. Yes. For all surgical patients, yes.

17:39:25 7 Q. You'd agree that 3M knew that bacteria was
17:39:30 8 harbored in both the hose and the machine; correct?

17:39:32 9 MR. BLACKWELL: I object as asked and
17:39:33 10 answered.

17:39:34 11 A. Yes.

17:39:35 12 Q. And 3M knew that the intake for the Bair
17:39:39 13 Hugger machines is near the floor; correct?

17:39:42 14 A. It -- if you --

17:39:43 15 MR. BLACKWELL: I object to the form of the
17:39:44 16 question.

17:39:44 17 A. If -- if the unit is placed on the floor,
17:39:47 18 yes. But many times it's placed on an IV pole or on a
17:39:50 19 rolling cart.

17:39:50 20 Q. Okay. 3M knew that operating room personnel
17:39:54 21 considered areas beneath the operating room table to
17:39:57 22 be unsterile; correct?

17:39:59 23 A. Yes.

17:39:59 24 Q. And 3M also knew that a filter would not
17:40:03 25 prevent bacteria from passing into the hose; correct?

17:40:05 1 A. No.

17:40:11 2 Q. Is the -- is --

17:40:13 3 Is it your testimony today or is it 3M's
17:40:15 4 testimony that the filter that was associated with the
17:40:17 5 Bair Hugger would prevent particles from migrating to
17:40:22 6 the distal end of the hose?

17:40:24 7 A. Well it -- it prevents -- it pre -- prevents
17:40:27 8 particles from entering the machine and migrating to
17:40:32 9 the end of the hose.

17:40:33 10 Q. It prevents some particles, perhaps, --

17:40:36 11 A. Yes.

17:40:37 12 Q. -- from entering.

17:40:37 13 A. Correct.

17:40:38 14 Q. But not all particles; agreed?

17:40:41 15 A. Certainly not all.

17:40:42 16 Q. All right. Would you agree that 3M
17:40:47 17 didn't -- did not and Arizant did not do any testing
17:40:51 18 with respect to whether or not contaminants inside the
17:40:53 19 machine could ultimately migrate to the surgical
17:40:56 20 field?

17:41:00 21 A. To my knowledge, we did not conduct studies
17:41:03 22 like that.

17:41:09 23 Q. And you'd agree that 3M and Arizant never
17:41:12 24 did any testing with respect to whether the filter was
17:41:16 25 effective in eliminating transmission of all bacterial

17:41:20 1 colonies; right?

17:41:21 2 MR. BLACKWELL: Object to the form of the
17:41:22 3 question.

17:41:25 4 A. That type of study has not been conducted.
17:41:29 5 However, MERV 14 is the ASHRAE standard filter for
17:41:36 6 preventing bacteria from being introduced into a --
17:41:41 7 a -- a hospital setting.

17:41:53 8 Q. And you'd agree that 3M has not provided --
17:41:56 9 and Arizant I should say -- has not provided any
17:41:59 10 warnings on possible contamination with respect to
17:42:02 11 machines in any of the service or technical manuals;
17:42:06 12 correct?

17:42:06 13 MR. BLACKWELL: I object to the form of the
17:42:07 14 question.

17:42:12 15 A. Would -- I'm sorry. Would you repeat the
17:42:14 16 question?

17:42:14 17 Q. I'll do my best.

17:42:16 18 You'd agree that -- that 3M and Arizant have
17:42:19 19 not provided any warnings about possible contamination
17:42:23 20 of the machines in either service or technical
17:42:25 21 manuals.

17:42:28 22 A. There is a filter-change recommendation in
17:42:31 23 the -- in the manual, so -- so there's a -- there's a
17:42:39 24 service schedule for replacing the filter in the
17:42:42 25 machine as it gets older.

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17:42:44 1 Q. And -- and MERV 14 is not the standard for
17:42:47 2 ultraclean filtration; is it?

17:42:50 3 A. No. But most operating rooms are not
17:42:54 4 ultraclean filtration.

17:42:56 5 Q. And that was known to 3M as well.

17:42:58 6 A. Yes.

17:42:59 7 Q. And you'd agree that there are no
17:43:02 8 instructions provided about cleaning the inside of the
17:43:06 9 Bair Hugger machine or the hoses; correct?

17:43:08 10 A. The inside? No.

17:43:12 11 Q. All right. And that's both the machine and
17:43:13 12 the hoses; correct?

17:43:14 13 A. Correct.

17:43:15 14 Q. And you'd agree that 3M has not undertaken
17:43:22 15 or implemented any design changes that could have made
17:43:25 16 the Bair Hugger devices safer, such as an
17:43:29 17 antimicrobial protection on the inside of the hose or
17:43:33 18 a distal hose filter at the end of the hose; correct?

17:43:36 19 MR. BLACKWELL: I object to the form of the
17:43:37 20 question.

17:43:37 21 A. Well I'm not -- I'm not -- I'm not certain
17:43:40 22 that we would consider that safer, but we -- we
17:43:43 23 haven't implemented either of those two features.

17:43:46 24 Q. All right. And a HEPA filter was considered
17:43:53 25 by 3M and ultimately rejected due to cost; correct?

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17:43:56 1 A. No.

17:43:57 2 MR. BLACKWELL: Object as asked and

17:43:58 3 answered.

17:44:00 4 A. [REDACTED]

17:44:03 5 [REDACTED]

17:44:05 6 [REDACTED]

17:44:10 7 [REDACTED]

17:44:11 8 [REDACTED]

17:44:13 9 [REDACTED]

17:44:14 10 [REDACTED]

17:44:18 11 [REDACTED]

17:44:21 12 [REDACTED]

17:44:56 13 [REDACTED]

17:45:00 14 [REDACTED]

17:45:05 15 [REDACTED]

17:45:11 16 [REDACTED]

17:45:18 17 [REDACTED]

17:45:24 18 [REDACTED]

17:45:29 19 [REDACTED]

17:45:35 20 [REDACTED]

17:45:37 21 [REDACTED]

17:45:39 22 [REDACTED]

17:45:41 23 [REDACTED]

17:45:44 24 [REDACTED]

17:45:46 25 [REDACTED]

17:45:48 1 Q. And the 500 series, the predicate product is
17:45:52 2 the 200 series; right?

17:45:54 3 A. Yes.

17:45:54 4 Q. And on the 200 series products there was a
17:45:59 5 warning about a risk of airborne contamination;
17:46:02 6 correct?

17:46:02 7 MR. BLACKWELL: I object to the form of the
17:46:03 8 question, and outside the scope of this witness's
17:46:05 9 30(b)(6) designation.

17:46:07 10 A. I -- I'm not certain of that.

17:46:09 11 Q. All right.

17:46:39 12 (Exhibit 351 was marked for
17:46:41 13 identification.)

17:46:41 14 BY MS. ZIMMERMAN:

17:46:45 15 Q. I'll represent to you that this is a
17:46:47 16 photograph from the out -- actually, from the inside
17:46:50 17 lid -- (clearing throat) pardon me -- inside lid of
17:46:53 18 the Bair Hugger 200 series, and do you see on the --
17:46:59 19 Is it number four?

17:47:04 20 A. Four and five, yes.

17:47:06 21 Q. Yes. And you see that there is a warning,
17:47:09 22 then, provided there about the risk of airborne
17:47:12 23 contamination; correct?

17:47:13 24 A. In -- in warning number five, yes.

17:47:19 25 Q. Yes. And you'd agree that there is no

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17:47:22 1 warning on the 500 series about the risk of airborne
17:47:25 2 contamination; correct?

17:47:26 3 A. That's correct. However, this --

17:47:31 4 Just to be clear, this warning does state
17:47:33 5 that "The possibility of airborne contamination should
17:47:36 6 be considered if patients with infected wounds are
17:47:39 7 treated with the Bair Hugger," so I think what's being
17:47:42 8 warned about here is the potential of moving bacteria
17:47:50 9 from an infected wound to somewhere else with the Bair
17:47:53 10 Hugger, not infecting a -- a surgical wound. So the
17:47:58 11 wound is already infected here.

17:48:00 12 Q. You'd agree that the -- the issue of
17:48:03 13 contamination through bacteria -- through airborne
17:48:08 14 contamination of bacteria is -- is the subject of
17:48:11 15 a -- the claims in this lawsuit; right?

17:48:13 16 A. Yes.

17:48:15 17 Q. All right. And at least at the time of the
17:48:18 18 200 series it was known to then Augustine Medical,
17:48:22 19 which became Arizant, which became 3M, that bacteria
17:48:25 20 could become aerosolized and eventually potentially
17:48:29 21 contaminate and infect somebody; correct?

17:48:31 22 MR. BLACKWELL: Yeah. I object to the form
17:48:34 23 of the question, also object as beyond the scope of
17:48:35 24 this witness's 30(b)(6) designation, as well as this
17:48:39 25 Exhibit 351, which doesn't have a Bates number, and

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17:48:42 1 it's not clear what Bair Hugger unit it applies to.

17:48:48 2 Q. You can answer the question.

17:48:50 3 A. I'm sorry, what was the question again?

17:48:52 4 Q. The risk of airborne contamination through
17:48:55 5 bacteria was known at the time that this warning was
17:48:57 6 placed on whatever this machine was; correct?

17:48:59 7 MR. BLACKWELL: Object for lack of
17:49:01 8 foundation, I object to the form of the question, as
17:49:03 9 well as beyond the scope of this witness's 30(b)(6)
17:49:06 10 designation.

17:49:07 11 A. And again, I --

17:49:08 12 As I read the warnings here, it seems to me
17:49:11 13 that these warnings apply to wounds that are already
17:49:14 14 infected and perhaps the desire not to spread bacteria
17:49:21 15 from infected wounds to the operating room.

17:49:24 16 Q. And that --

17:49:25 17 A. This is not -- this is not the same thing as
17:49:28 18 infecting a -- a -- a wound.

17:49:30 19 Q. Right. But the ques --

17:49:31 20 MR. BLACKWELL: Can I ask just for
17:49:32 21 clarification? Is Exhibit 351 a warning that relates
17:49:35 22 to models -- either the 700 series or the 500 series?

17:49:39 23 MS. ZIMMERMAN: Mr. Blackwell, my question
17:49:41 24 to the witness has to do with changes to -- in the
17:49:43 25 warnings provided on the 500 and the 700 series, and I

17:49:46 1 asked him about changes that were made to the
17:49:49 2 predicate device, which was the 200, which is what
17:49:51 3 this is a picture of.

17:49:52 4 MR. BLACKWELL: So Exhibit 351 relates to
17:49:54 5 the predicate device, the 200.

17:49:56 6 MS. ZIMMERMAN: Exactly. And the question
17:49:57 7 ultimately is: Why was the warning removed when we
17:50:01 8 got to the 500 series?

17:50:03 9 A. Well there's another difference, too, and
17:50:05 10 that is that the 200 was not intended to be used in
17:50:07 11 the operating room.

17:50:07 12 Q. Right. And -- and I'm aware of that, Mr.
17:50:09 13 Van Duren. My question really is -- has to do with
17:50:13 14 the knowledge that was available to the company
17:50:16 15 broadly at that time.

17:50:19 16 There -- there was some knowledge, based on
17:50:20 17 the fact that there is a warning of airborne
17:50:23 18 contamination, that contamination could be airborne;
17:50:27 19 correct?

17:50:27 20 A. Yes.

17:50:28 21 Q. Okay. And -- and despite that fact, there
17:50:31 22 is no warning on the 500 series of the Bair Hugger
17:50:33 23 device about risk of airborne contamination; correct?

17:50:36 24 A. That's correct.

17:50:39 25 Q. And that's despite the fact that the medical

17:50:42 1 care professionals rely on the company to warn about
17:50:46 2 risks; correct?

17:50:47 3 MR. BLACKWELL: I object to the form of the
17:50:48 4 question.

17:50:48 5 A. The risks that are known of, known about,
17:50:53 6 yes.

17:50:53 7 Q. All right. And -- and -- and al --

17:50:54 8 That's also despite the fact that medical
17:50:57 9 care professionals rely on the company to provide
17:50:59 10 rules for safe use of a device; correct?

17:51:02 11 MR. BLACKWELL: I object to the form of the
17:51:03 12 question.

17:51:03 13 A. Yes.

17:51:04 14 And it's very likely that the hazard
17:51:06 15 analysis that occurred subsequent to the development
17:51:09 16 of this device recognized that the risk index was
17:51:13 17 either too low or zero and removed that warning from
17:51:18 18 the labeling.

17:51:20 19 MS. ZIMMERMAN: I'm going to move to strike
17:51:21 20 as non-responsive.

17:51:22 21 Q. Are you aware of any testing that -- that
17:51:24 22 showed that there was not airborne risk of
17:51:26 23 contamination --

24 A. I'm not.

17:51:28 25 Q. -- conducted by this study?

17:51:29 1 A. I'm not.

17:51:30 2 Q. Or I'm sorry, conducted by the company.

17:51:33 3 A. No, I am not.

17:51:34 4 Q. Okay. So it's pure speculation on your
17:51:36 5 part.

17:51:37 6 Turning to the 700 series Bair Hugger,
17:51:39 7 was -- was there any changes on the warnings as
17:51:41 8 between the 700 series and the 500 series Bair
17:51:45 9 Huggers?

17:51:45 10 A. I believe there were some changes.

17:51:49 11 Q. And what were those changes?

17:51:50 12 A. I believe the recommendation not to hose
17:51:54 13 patients with the -- with the end of the nozzle was
17:51:57 14 added.

17:51:57 15 Q. And hose --

17:51:59 16 And hosing is a practice of essentially
17:52:01 17 using the machine without the disposable blanket
17:52:04 18 attached; correct?

17:52:04 19 A. That's right.

17:52:05 20 Q. All right. Were there any other changes?

17:52:07 21 A. I'm -- I'm --

17:52:09 22 I suspect there are. I don't -- I don't
17:52:11 23 know which ones changed between the two models though.

17:52:15 24 Q. So as you sit here today, the only change
17:52:16 25 that you are aware of between the 500 and 700 series

17:52:19 1 with respect to the warnings has to do with the

17:52:22 2 warning not to engage in hosing; correct?

17:52:27 3 A. That's correct.

17:52:28 4 Q. All right. And you'd agree that there's no

17:52:30 5 warning on the 700 series, again, regarding the risk

17:52:34 6 of airborne contamination; correct?

17:52:35 7 A. That's correct.

17:52:37 8 Q. And again, that's despite the fact that the

17:52:39 9 risk of airborne contamination was in fact known to

17:52:42 10 the company at that time; correct?

17:52:45 11 MR. BLACKWELL: I object to the form of the

17:52:46 12 question.

17:52:51 13 A. It --

17:52:52 14 Well, it was included as a warning on the

17:52:54 15 model 200, yes.

17:52:55 16 Q. Okay. I'm going to turn to topic number

17:53:04 17 eight, which is data or research supporting the claim

17:53:07 18 that the Bair Hugger blankets act as an additional

17:53:10 19 filter or otherwise reduce the potential for

17:53:12 20 contamination in the operating room. You're prepared

17:53:15 21 to testify about that today as well; correct?

17:53:17 22 A. Yes.

17:53:18 23 Q. And I think you had some questions posed to

17:53:23 24 you earlier today by my colleague, Mr. Assaad,

17:53:26 25 regarding the Avidan study. Do you recall that?

17:53:28 1 A. Yes.

17:53:28 2 Q. Is there any other study that -- that 3M is
17:53:31 3 aware of that addresses the issue of whether a blanket
17:53:37 4 might act as an additional filter?

17:53:39 5 A. I think Avidan is probably the first
17:53:42 6 indication we had of -- of that. I'm not aware as I
17:53:48 7 sit here of another study like that.

17:53:50 8 Q. All right. And that was 1993?

17:53:52 9 A. I think it was around that timeframe, yes.

17:53:54 10 Q. All right. Are you aware or is the company
17:53:57 11 aware of any other data that supports the notion that
17:54:01 12 the blanket itself may act as an additional filter?

17:54:07 13 A. To my knowledge, we haven't conducted any
17:54:11 14 internal testing to confirm that.

17:54:14 15 Q. So no -- no testing has been done by the
17:54:17 16 company with respect to whether the disposable
17:54:21 17 blankets themselves may act as some sort of filter;
17:54:25 18 correct?

17:54:25 19 A. That's correct.

17:54:25 20 Q. All right. And Mr. Assaad asked you some
17:54:37 21 questions about that Avidan study. You're aware that
17:54:40 22 ultimately the author concluded that forced-air
17:54:42 23 warming systems, such as the Bair Hugger, are a
17:54:44 24 potential source of nosocomial infections; correct?

17:54:47 25 MR. BLACKWELL: I object to the form of the

17:54:48 1 question.

17:54:49 2 A. He -- he speculated that was true.

17:54:57 3 Q. And again, that -- that Avidan study was --

17:55:00 4 was done on the Bair Hugger 505; correct?

17:55:03 5 MR. BLACKWELL: Object as asked and

17:55:04 6 answered.

17:55:04 7 A. Yes.

17:55:05 8 Q. [REDACTED]

17:55:09 9 [REDACTED]

17:55:13 10 [REDACTED]

17:55:16 11 [REDACTED]

17:55:17 12 [REDACTED] [REDACTED]

17:55:19 13 [REDACTED] [REDACTED] [REDACTED]

17:55:25 14 [REDACTED]

17:55:27 15 [REDACTED]

17:55:31 16 [REDACTED]

17:55:33 17 [REDACTED]

17:55:33 18 [REDACTED] [REDACTED]

17:55:34 19 [REDACTED] [REDACTED] [REDACTED]

17:55:36 20 [REDACTED] [REDACTED]

17:55:43 21 [REDACTED]

17:55:48 22 [REDACTED]

17:55:55 23 [REDACTED] [REDACTED]

17:55:58 24 [REDACTED] [REDACTED]

17:56:09 25 [REDACTED]

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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17:58:47	1	[REDACTED]	
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17:59:00	9	[REDACTED]	[REDACTED]
17:59:01	10	[REDACTED]	[REDACTED]
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17:59:27	18	[REDACTED]	
17:59:29	19	[REDACTED]	[REDACTED]
17:59:30	20	[REDACTED]	[REDACTED]
17:59:32	21	[REDACTED]	
17:59:35	22	[REDACTED]	[REDACTED]
17:59:36	23	[REDACTED]	[REDACTED]
17:59:39	24	[REDACTED]	[REDACTED]
17:59:39	25	[REDACTED]	[REDACTED]

17:59:43 1 [REDACTED]

17:59:48 2 [REDACTED] [REDACTED]

17:59:49 3 [REDACTED] [REDACTED] [REDACTED]

17:59:55 4 [REDACTED]

17:59:55 5 [REDACTED] [REDACTED]

17:59:56 6 Q. All right. Are you aware of the FDA and CDC

18:00:10 7 committee reports with respect to blowing air in

18:00:12 8 operating rooms?

18:00:14 9 A. I'm aware of a HICPAC meeting where that was

18:00:18 10 discussed.

18:00:19 11 Q. Yes. And that -- that has to do with

18:00:23 12 the -- the Sorin 3T heater/cooler device; correct?

18:00:27 13 A. Yes.

18:00:27 14 MR. BLACKWELL: I object to these questions

18:00:29 15 as beyond the scope of the 30(b)(6) designation.

18:00:31 16 Q. All right. And -- and -- and 3M has had

18:00:34 17 various representatives participate in telephone

18:00:38 18 conferences and other meetings with respect to the

18:00:40 19 HICPAC conclusions; correct?

18:00:41 20 MR. BLACKWELL: Beyond the scope of the

18:00:43 21 30(b)(6) designation.

18:00:44 22 A. I mean I'm not -- I'm not sure what you're

18:00:47 23 asking. We -- we've had conversations, yes.

18:00:50 24 Q. Yeah.

18:00:51 25 A. Yes.

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18:00:51 1 Q. And -- and have participated, in fact, in --
18:00:54 2 in the telephone conferences that the FDA and HICPAC
18:00:58 3 have provided.

18:01:00 4 MR. BLACKWELL: Same objection.

18:01:03 5 A. We have employees who participate in the
18:01:04 6 HICPAC meetings in -- at the FDA.

18:01:08 7 Q. All right. And so you're -- the --

18:01:10 8 The company is aware, then, that according
18:01:12 9 to the CDC and -- and the HICPAC guidelines, that
18:01:16 10 blowing air in an operating room is to be avoided;
18:01:19 11 correct?

18:01:19 12 MR. BLACKWELL: Object as beyond the scope
18:01:21 13 of his designation, and I object as to form,
18:01:23 14 foundation.

18:01:26 15 A. I'm aware of that statement in the HICPAC
18:01:29 16 meeting minutes in the context of the Sorin
18:01:33 17 heater/cooler unit.

18:01:34 18 Q. Right. And the HICPAC -- you're aware
18:01:37 19 then --

18:01:37 20 The company is aware that HICPAC reaches a
18:01:40 21 conclusion that essentially all non-essential medical
18:01:44 22 equipment that blows air should be out of the
18:01:46 23 operating room; correct?

18:01:47 24 MR. BLACKWELL: Object as beyond the scope
18:01:48 25 of his designation, object as to form, lack of

18:01:52 1 foundation.

18:01:52 2 A. I believe that was the opinion of one of the
18:01:55 3 members of the meeting, yes.

18:01:57 4 Q. All right.

18:02:22 5 MS. ZIMMERMAN: If you want to just take a
18:02:24 6 two- or three-minute break, I may be able to wrap this
18:02:27 7 up pretty quickly.

18:02:29 8 THE REPORTER: Off the record, please.

18:07:06 9 (Recess taken.)

18:07:06 10 MS. ZIMMERMAN: All right. Mr. Van Duren,
18:07:09 11 we don't have any more questions of you today. We're
18:07:11 12 going to hold this deposition open pending the
18:07:13 13 conclusion of the rest of the 30(b)(6) topics.

18:07:16 14 Thank you.

18:07:16 15 MR. BLACKWELL: We obviously believe it's
18:07:18 16 closed, but we've had our say.

18:07:20 17 THE REPORTER: Off the record, please.

18:07:23 18 (Deposition recessed/concluded.)

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1 C E R T I F I C A T E

2 I, Richard G. Stirewalt, hereby certify that
3 I am qualified as a verbatim shorthand reporter, that
4 I took in stenographic shorthand the deposition of
5 ALBERT P. VAN DUREN at the time and place aforesaid,
6 and that the foregoing transcript is a true and
7 correct, full and complete transcription of said
8 shorthand notes, to the best of my ability.

9 Dated at Deerwood, Minnesota, this 9th day
10 of March, 2017.

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17 RICHARD G. STIREWALT

18 Registered Professional Reporter

19 Notary Public

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1 C E R T I F I C A T E

2 I, ALBERT P. VAN DUREN, hereby certify that
 3 I have carefully read the foregoing transcript, and
 4 that the same is a true and complete, full and correct
 5 transcription of my deposition, except:

6 PAGE/LINE CHANGE REASON

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17 ALBERT P. VAN DUREN

18 Deponent

19

20 Signed and sworn to before me this ____ day of
 21 April, 2017.

22

23

24

Notary Public

25